CardioSys
Operator's Manual

Version 4.1
227 498 02 GA(e) Revision A

marquette

A GE Medical Systems Company

The product CardioSys bears the CE marking

CE-0366

indicating its compliance with the provisions of the Council Directive 93/42/EEC about medical devices and fulfills the essential requirements of Annex I of this directive.

The product fully complies with the electromagnetic immunity requirements of standard EN 60601-1-2 “Electromagnetic Compatibility – Medical Electrical Equipment”.

The device is in radio-interference protection class B in accordance with EN 55011.

The EC Declaration of Conformity covers only the accessories listed in the “Equipment” section.

This manual reflects software version 4.1.

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Revision History

This document is subject to the Marquette Hellige change order system. The revision code, a letter that follows the document part number, changes with every update of the manual.

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General Information

* This manual is an integral part of the instrument and describes its normal use. It should always be kept close to the equipment. Observance of the manual is a prerequisite for proper instrument performance and correct operation and ensures patient and operator safety.

* The symbol ⚠ denotes: Refer to Operator's Manual! It serves as an indicator for important facts to be noted when operating the instrument.

* Information which refers only to certain versions of the instrument is accompanied by the catalog number(s) of the instrument(s) concerned. The catalog number is given on the instrument nameplate.

* For detailed safety information, please refer to section 1.3 "For your safety".

* Patient safety, specified measuring accuracy, and interference-free operation can be guaranteed only if original Marquette Hellige devices are interconnected (e.g. basic units and plug-in modules).

* Only use accessories which are listed in this manual and which have been tested in combination with the device (e.g. patient cables, electrodes, transducers, sensors, consumables, etc.). If you use accessories or consumables from other manufacturers, Marquette Hellige does not guarantee safe operation or functioning of the device.

* The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers.

* Marquette Hellige is responsible for the effects on safety, reliability, and performance of the equipment, only

  – if assembly operations, extensions, readjustments, modifications, or repairs are carried out by Marquette Hellige or by persons authorized by Marquette Hellige.

  – if the instrument is used in accordance with the instructions for use.

* All publications are in conformity with the instrument specifications and IEC publications on safety of electromedical equipment valid at printing date. All rights are reserved for instruments, circuits, techniques, and names appearing in the manual.

* On request Marquette Hellige will provide a service manual.

* The Marquette Hellige quality management system complies with the DIN EN ISO 9001 and EN 46001 Standards.

1. Introduction to CardioSys

In this section you will find

– an overview of the CardioSys features and capabilities and of the available software options

– a survey of the CardioSys system components

– points to note during system operation

– instructions on putting the system into operation

1.1 Program Features

CardioSys is a PC-based system for ECG recording, spirometry tests and ambulatory blood-pressure examinations. The following options are available to enhance the program functions:

Basic Software Package (RESB)
- 12-lead ECG acquisition (resting ECG, STAT ECG)
- recording of spirometry tests
- downloading of data from TONOPORT IV/IVa (ambulatory blood pressure)
- downloading of data from electrocardiographs EK 53, EK 56, EK 512, CardioSmart
- data management for all operating modes
- BDT interface

Resting ECG Measurement (RESM)
- measurement of 12 ECG leads acquired simultaneously
- tabular presentation of the measured values
- editing of measuring marks
- direct comparison of 2 resting ECGs

Resting ECG Interpretation (RESI)
- interpretation of the measured resting ECG with detailed explanations
- medication and the patient's age are taken into account
- reanalysis after modification of the measuring marks

3-Lead Exercise ECG (ERG1)
- 3-lead recording and display
- control of all Marquette Hellige ergometers
- creation of custom protocols and phases (depending on ergometer model)

Upgrade for 12-Lead Exercise ECG (ERG2)
- optional recording of 3, 6 or 12 ECG leads
- 12-lead ST measurement
- automatic or manual determination of the J+X point
- presentation of the ST medians
- presentation of the resting ECG complex and of the current ST beat for direct comparison
- arrhythmia analysis and presentation during the test

Storage of the Full-Disclosure ECG (EGMO)
- continuous storage of up to 12 ECG leads
- color-coded arrhythmias
- any segment of the full-disclosure ECG can be zoomed and stored

Exercise Test Expert Mode (ERG3)
- optional presentation of ST level and slope in the form of a bar diagram or ST medians with reference marks
- manual editing of the E, J, and J+X points
- scrolling to previous stages during the exercise test
- direct cross-referencing from trends to full-disclosure ECG (final report)

In-Test Reports (ESTA)
- automatic or manual printout during the exercise test via laser printer or thermal printer
- report formats for laser printer: medians + 12-lead ECG (approx. 4 seconds)
- report formats for thermal printer:
  - 10-second segments of the 12-lead ECG in different formats
  - comparative medians + 12-lead ECG
  - continuous rhythm (6 or 12 leads)

Late Potential Analysis (AVER)
- recording of ventricular late potentials
- recording of the standard vectors X, Y, Z (uncorrected)
- manual editing of QRS onset and offset

Data Storage on File Server (NETS)
- storage of the procedure data on the network file server

Monitoring of Remote Test Stations (ERGM)
- during the exercise test data are continuously sent via the network
- the following data can be viewed at any of the work-stations in the network:
  - station name
  - 6-lead ECG, leads selectable
  - information on the exercise test and on the ergometer
  - HR and blood pressure
  - ST measurement results (resting beat, current beat)

Task List (OMAN)
- patient selection on task list
- task list created by host program (hospital information system, medical reimbursement program, etc.)
- supports BDT format
- examination results are returned to the requesting system

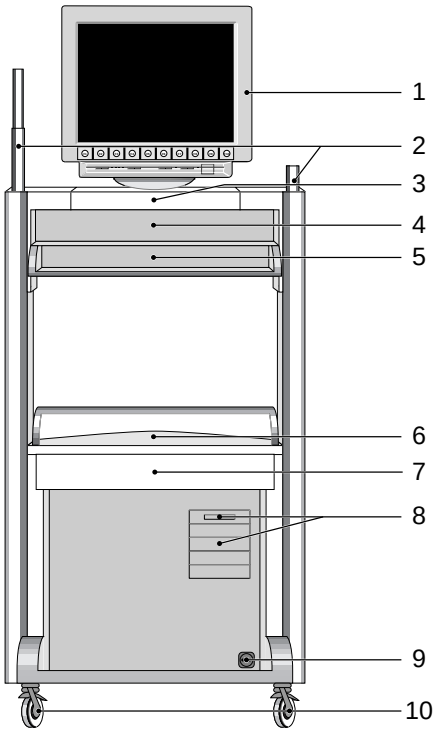
ECG History (ECGH) requires hardlock
- display of the median beats from up to 5 selectable resting ECGs for visual comparison or printout
- 3D presentation of the medians for serial comparison

Review Manager (REVM) requires hardlock
- users can review and confirm the examination results
- name of the physician who confirmed the results is automatically entered in the patient file
- display of examination procedures according to different criteria (confirmed, unconfirmed, all)

Cardio Mailbox (CBOX) requires hardlock
- transmission of multiple procedures via a modem to CardioSys/CardioSoft
- storage of multiple procedures on storage medium
- reception of multiple procedures via a modem (from CardioSys/CardioSoft or CardioSmart)

1.2 System Configuration and Function, Setting Up the PC

CardioSys is a system cart centering around a PC and software programs. Figure 1-1 shows the CardioSys system cart.



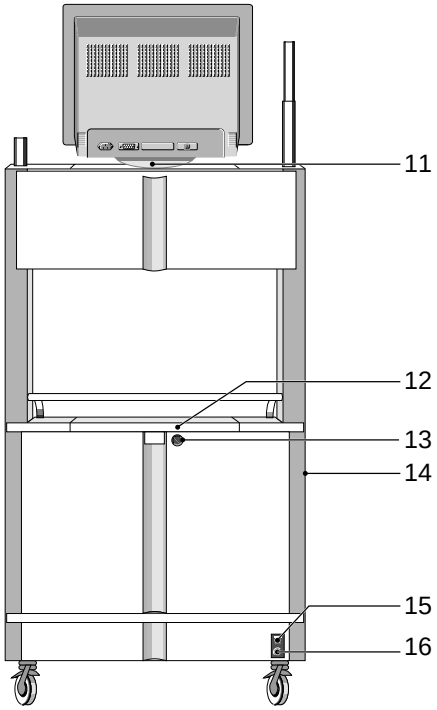


Figure 1-1. CardioSys system cart

1 *Monitor*
2 *Supports for electrode application system or respiration flow sensor*
3 *Monitor support*
4 *Tray for PC keyboard*
5 *Tray for function keyboard and mouse*
6 *Tray (e.g. for printer)*
7 *Accessory drawer*
8 *Power button, floppy disk drive and drive bays (streamer, MO drive)*
9 *Shelf with power connector for defibrillator*
10 *Conductive castors (front castors locking)*
11 *Monitor retaining strip*
12 *Connection panel (under lid)*
13 *Lid lock*
14 *Power switch (removes power from the system)*
15 *Power input with instrument fuses*
16 *Potential equalization pin*

The lid should only be opened by Marquette Hellige staff or by factory-trained personnel.

Biocompatibility

The parts of the product described in this operator manual, including all accessories, that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards. If you have questions in this matter, please contact Marquette Hellige GmbH or its representatives.

The system comes pre-installed and is ready for operation. All connections for system components and peripheral devices (including the patient cable) are located under the lid (12) which can be opened with a tool only.

The program is a Windows application. Its scope can be expanded by activation of individual optional programs. This manual describes the program with all options included. If you have not purchased one or the other option, simply skip the corresponding sections.

Being familiar with PC programs may be a help, but in this manual you will find everything you need to know about using a mouse and a PC keyboard.

Whenever you are unsure about a program function or operating step, just click on the Help button to obtain online information.

Access to the program is restricted to registered users. At the time a user is registered, the password and the user's rights are assigned (user, physician, with or without the right to make system changes).

1.3 For Your Safety

The safety information given below is divided into the categories “Danger”, “Warning” and “Caution”.

indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury and/or damage to the equipment.

☞ ***provides application tips or other useful information to assure that you get the most from your equipment.***

☞ ***CardioSys is a class I system.***

Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the system’s nameplate. If this is not the case, do not connect the system to the power line.

Do not use extension cables with multiple power outlets to connect the system to the power line.

Before putting the system into operation visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately.

When disconnecting the system from the power line, remove the plug from the wall outlet first. Then you may disconnect the power cord from the device. If you do not observe this sequence, there is a risk of coming into contact with line voltage by inserting metal objects, such as the pins of electrode leads, into the sockets of the power cord by mistake.

CardioSys can be operated on an uninterruptible power supply (UPS). The UPS should not be disconnected from the power line for prolonged periods of time to prevent deep discharging of the battery. For this reason, switch the CardioSys system off and on with the system's own power switch and do not use the switch of the UPS or the main power switch of the office.

As a general rule, the UPS must first be connected to the power line and switched on; then you may switch on CardioSys.

Do not switch on the CardioSys system during a power outage.

Only the CardioSys system may be connected to the UPS.

The UPS must be installed within the medically used room, but outside the patient environment.

Observe the information given in the UPS user manual.

The power socket of the CardioSys system cart is reserved for a defibrillator for recharging of the defibrillator battery (max. power 30 VA).

All devices of a system must be connected to the same power supply circuit. Devices which are not connected to the same circuit must be electrically isolated when operated (electrically isolated RS232 interface).

Set up the device in a location which affords sufficient ventilation. The ventilation openings of the device must not be obstructed. The ambient conditions specified in the "Technical Specifications" section must be ensured at all times.

The system should be set up to provide the operator an unobstructed view of the control panel.

Devices intended for emergency application must not be stored or transported at temperatures which cause moisture condensation at the application site. Wait until all moisture condensation has evaporated before using the device.

If the system is used as an emergency device, a second ECG recorder must be available.

The device is not intended for intracardiac application.

The device is not suitable for operation in areas where an explosion hazard may occur. Explosion hazards may be caused by the use of flammable anesthetics, skin-cleansing agents and disinfectants. Great care must be exercised when the monitor is used in an oxygen-enriched atmosphere. The atmosphere is considered to be oxygen-enriched when the room air contains more than 25% of oxygen or nitrous oxide.

The patient signal input is labelled with the ⏚ ♥ ⏚ symbol, indicating that it is protected against damage resulting from defibrillation and electrocautery. Nevertheless extreme care must be taken when devices which are directly connected to the patient remain applied during defibrillation. The distance between ECG electrodes and defibrillation paddles should be at least 6 in./15 cm. If in doubt, disconnect the patient cable from the device while applying the defibrillation pulse.

Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason do not operate the system in the vicinity of equipment emitting strong electromagnetic radiation (X-ray equipment, diathermy systems or MRI devices).

Only use the original Marquette Hellige patient cable. Do not connect other signal sources to the cable.

With all peripheral devices connected, CardioSys represents a medical system. It fulfills the requirements of the system standard IEC 60601-1-1. The entire system may be operated in the patient environment.

If the system cart is installed in the patient environment, only the special printer modified by Marquette Hellige and equipped with an additional protective earth connection (potential equalization) may be operated. Observe the assembly instructions supplied with the printers.

For stress-test examinations, a defibrillator and a pacemaker, regularly checked for proper functioning, must be readily accessible.

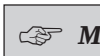
Extreme care must be exercised when using medical electrical equipment. Many parts of the man/machine circuit are conductive, such as the patient, connectors, electrodes, transducers. It is very important that these conductive parts do not come into contact with other grounded, conductive parts when connected to the isolated patient input of the device. Such contact would bridge the patient's isolation and cancel the protection provided by the isolated input. In particular, there must be no contact of the neutral electrode and ground.

Devices may only be interconnected with each other or to parts of systems when it has been made certain that there is no danger to the patient, the operators, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned or other informed experts as to whether there is any possible danger to the patient, the operator, or the environment as a result of the proposed combination of devices. Standards IEC 60601-1-1/ EN 60601-1-1 must be complied with in all cases.

Liquids must not be allowed to enter the devices. Devices into which liquids have penetrated must be checked by a service technician before being used again.

Chemicals required for the application or maintenance of the devices must under all circumstances be stored, prepared and kept at hand in the containers provided by the manufacturer. Failure to observe this instruction may result in severe consequences for the patient.

CardioSys is not intended for use as a vital signs physiological monitor.



Medical technical equipment such as the CardioSys system must only be used by persons who have sufficient knowledge, who have received adequate training in the use of such equipment and who are capable of applying it properly.

Before using the system, the operator is obliged to verify that it is in correct working order and operating condition.

The operator must be familiar with the operation of the system.

Verify the performance of the system once a month.

Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children's reach.

At the end of its service life, CardioSys and its accessories must be disposed of in compliance with the applicable waste control regulations. If you have any questions in this matter, please contact Marquette Hellige GmbH.

Only use bicycle ergometers and treadmills that fulfill the applicable IEC 60601-1 requirements. CardioSys and the associated bicycle ergometer or treadmill must be connected to the same power supply circuit via separate wall outlets.

Only modems complying with the requirements of IEC 60950 or UL1950 may be connected to the system. Furthermore, the regulations applicable in the respective countries must be observed.
The modem must be set up inside the medically used room, but outside the patient environment.

Literature

Medical Device Directive

EN60601-1/1990 + A1:1993 + A2:1995: Medical electrical equipment. General safety standards

EN60601-1-1/9.1994 and A1 12.95: General safety standards. Standards for the safety of medical electrical systems.

IEC Publication 513/1994: Fundamental aspects of safety standards for medical equipment.

ROY, O.Z.: Summary of cardiac fibrillation thresholds for 60-Hz currents and voltages applied directly to the heart. Med. & Biol. Engn. & Computing 18: 657...659 (1980).

1.4 Putting the System Into Operation, Testing the Performance

* Before using the system for the first time, please read the information given in section 1.3 “For your Safety”.

* Turn on power with the main power switch (14).

* Switch on the system with the power button on the front panel (press for approx. 1 second).

Upon power up the PC runs automatic self tests. When the program detects any malfunctions, an error message is displayed. If no problem exists, you will see the usual Windows screen.

The ECG program too runs a self test when a signal acquisition screen is called up. If you do not see any error messages, the program and the computer are intact. Error messages may also appear during program operation.

– Do not run more than one other Windows application at the same time as CardioSys.

– Do not activate a Windows screen saver.

– Run a daily backup of your data (Appendix, sections 3.1).

– Quit the program in the prescribed manner (Chapter 5. “Deleting Examinations, Quitting the Program”) before switching off the system with the power button (8). Turn off power with the main power switch (14) only when the CardioSys cart will not be used for a prolonged period of time

1.5 Putting the Thermal Printer AR 200 Into Operation

Controls and indicators of the thermal printer are shown in Figure 1-2.

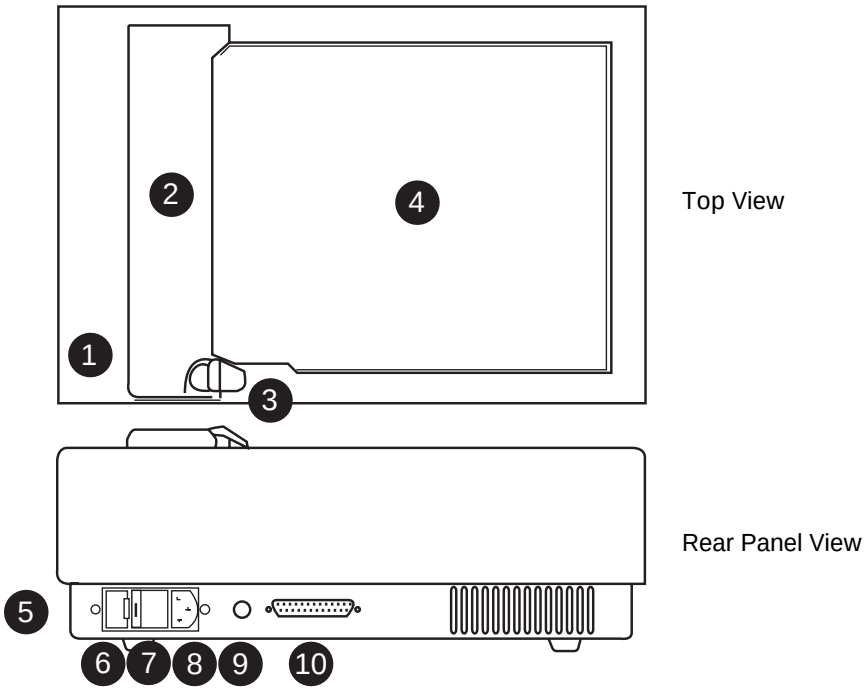


Figure 1-2. Controls and indicators of the thermal printer

1 *Green indicator, is lit when the printer is connected to the power line*
Yellow indicator, is lit to indicate a problem

2 *Paper guide*

3 *Paper tray door latch (lift latch to open door)*

4 *Paper tray door (the printer stops when the door is opened)*

Caution *When the door is open, take care to insure no small objects enter the printer.*

5 *Specification labels*

6 *Instrument fuses*

7 *Power button (printer is turned on with the system's main power switch)*

8 *Power input*

9 *Potential equalization pin*

10 *Parallel port*

Explanation of Symbols as Used on the Printer

printer problem

interface

fuse

Chart-Paper Loading

Before loading chart paper, make sure that the printer is switched off (button 7, Figure 1-2). The indicators will go off after a few seconds.

* Pulling upward on the paper tray door latch (3, Figure 1-2), open the paper tray door.

* Remove the cardboard backing of the old pad.

* When inserting the new pad, be aware of the following points:

  – the last sheets of the paper pad have a red stripe, so this side of the pad should be at the bottom of the tray

  – the black squares should be facing down and located on the side of the printer nearest the paper tray door latch

  – place the pad, including the cardboard backing, on the tray and remove the cardboard on the top.

* Pull the first sheet of the pad straight out over the paper guide, at the same time closing the paper tray door.

* Turn on the printer.

Do not attempt to operate the printer without thermal paper.
Do not pull on the sheets to remove them from the printer.
After loading a new pad, press keys Ctrl + ⇧ + 9) ***to ensure that the next printout starts at the top of the page.***

The thermal printer AR 200 does not require an additional protective earth connection (device in compliance with IEC 60601).

Printer Problems (Thermal Printer)

Problem	Remedy
Does not print and green LED labeled *Power* does not light	Check that power cable is properly connected. Check that power switch is on.
Does not print and green LED labeled *Power* is lit	Check if the CardioSys system power is on. Check cables between CardioSys system and printer. (May need to re-boot the system.) Check if the printer is out of paper. Check if there are any paper scraps caught under the print head.
Paper moves paper but recorder does not print	Paper is incorrectly loaded. Check that paper has correct pagination mark.

Reinstalling the Thermal Printer Driver

Usually the printer driver is installed. If it needs to be reinstalled, proceed as follows:

* Exit the application to Windows.
* From the Program Manager screen, call up
  - Main Group
  - Control Panel
  - Printers.
* Select “Add Printer”.
* Select “Install unlisted or updated driver”.
* Select “Install...”.
* Place the disk with the printer driver into the diskette drive and click on “OK”.
* Check the “Default printer” box.
* Select “Close”.
* Restart the application.

2. General Information on System Operation

This section describes some basic facts on program operation. You will learn

– how to use the program with a mouse

– how to enter data via the PC keyboard

– how to start the program

– how to select the language

2.1 Operating the Program with a Mouse

All operating steps required to run the program can be performed with a mouse. The screen layout permits swift program operation, and text entries via the keyboard have been reduced to a minimum. The system allows you to create libraries for various situations, which you can copy from the list to the respective text boxes in a dialog window, using the mouse.

If you are already familiar with the functions and handling of a PC mouse, you can skip this paragraph.

Some General Remarks on the PC Mouse

An arrow or mouse pointer appears on all screens. This mouse pointer moves around on the screen as you move the mouse on the table. Sliding the mouse to the right, for instance, shifts the pointer to the right.

The program can be used with a two or a three-button mouse (Figure 2-1). The buttons are operated with the index finger and the middle finger. The left button (index finger) controls almost all functions, while the right button (middle finger) is seldom used.

☞ ***When entering text via the keyboard, use the →\| key to move from text box to text box. This will save time as your hands can stay on the keyboard all the time.***

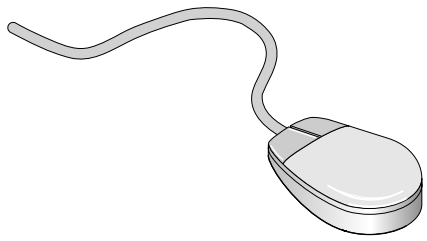


Figure 2-1. Mouse buttons

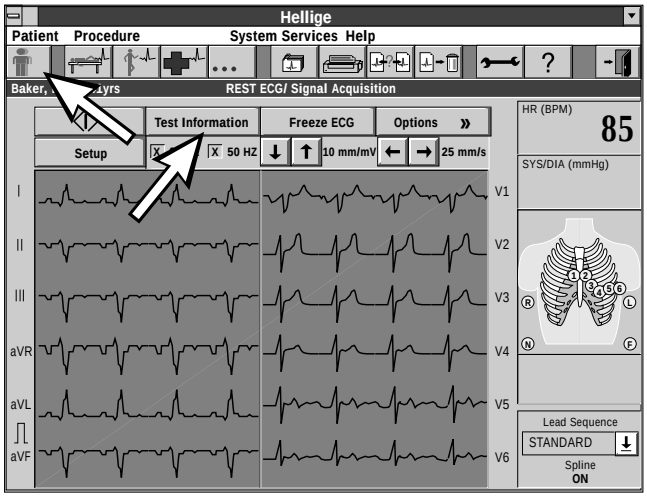


Figure 2-2. Screen with operating controls

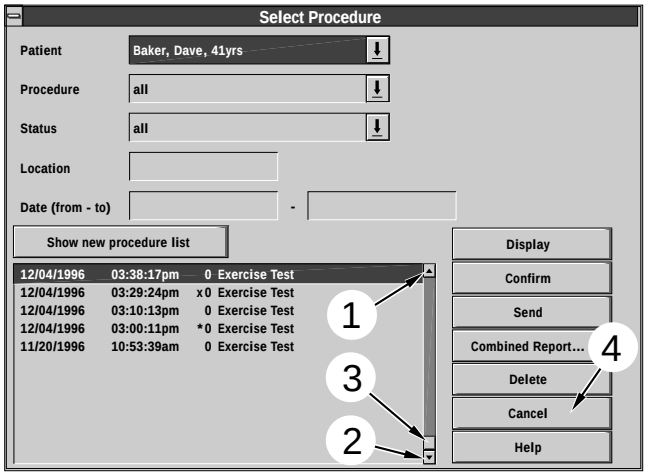


Figure 2-3. Excerpt from the procedure list

1 moves the list down (line by line)

2 moves the list up (line by line)

3 allows you to scroll to a general location in the list

4 clears the window without saving entries

The icons displayed on the monitor screen resemble the operating controls on a conventional ECG recorder (Figure 2-2).

To select a function you place the mouse pointer on the respective icon and press the left mouse button. You will see that the key on the screen is "pressed" at the same time.

Pressing a mouse button is also called "clicking". When, later on in this manual, you are asked to "double-click" this means that you should press the left mouse button twice in rapid succession.

On many screens you will see windows offering various selections (Figure 2-3).

To select an option, move the mouse pointer to the item and press the left mouse button. This selects the item, and the window disappears.

When a list of selections is too long to fit in the window, the window has a scroll bar at its right edge. Clicking the arrow at the upper end of the scroll bar moves the list down one by one (1, Figure 2-3), clicking the lower arrow moves the list up (2, Figure 2-3).

A so-called scroll box between the two arrows allows you to move quickly through the list by clicking the scroll box, holding the mouse button depressed, and dragging the box up or down (3, Figure 2-3).

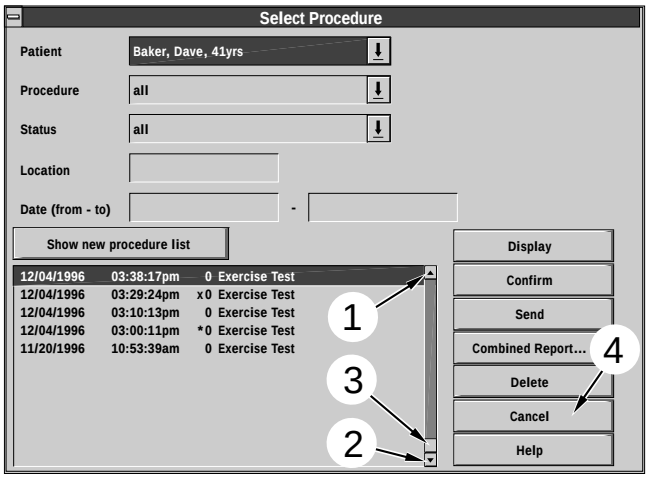


Figure 2-3. Excerpt from the procedure list

1 moves the list down (line by line)

2 moves the list up (line by line)

3 allows you to scroll to a general location in the list

4 clears the window without saving entries

> ☞ ***You clear the HELP window by clicking "File" and "Exit".***

The scroll box also indicates which section of the list is currently displayed. If the box is just below the upper arrow you see the top portion of the list, if the box is in the middle of the scroll bar, the middle portion of the list is on display, etc. When you see an horizontal scroll bar below a picture, the two arrows and the scroll box allow you to shift the picture left or right.

Some screens which offer various selections can be cleared by two methods: either with [OK] or with [Cancel] (Figure 2-3).

When you select [OK] the program accepts the selections made, with [Cancel], the selections will be ignored.

If you wish to highlight text click the first letter of the text block, hold the left mouse button down and drag the pointer to the last letter. Then release the mouse button. The marked text is displayed in reverse video.

To obtain information on program operation, click the [Help] button or [?].

2.2 The Most Important Keyboard Controls

Use the keyboard to enter text and numbers. The following is a description of functions which you do not know from a conventional typewriter. If you are already familiar with a PC keyboard, you may skip this section.

* The Backspace key (1, Figure 2-4) clears the characters from left to right, one by one.

* The cursor keys (5, Figure 2-4) are used to move the cursor up, down, right and left to any desired position in the text, for instance, to insert text (Ins key)

* or to delete text (Del key) (3, Figure 2-4).

* The Home and End keys (2, Figure 2-4) move the cursor to the first and last position in the text.

* With Return (4) and on Windows screens with TAB (6) you move the cursor to the beginning of a new, blank line.

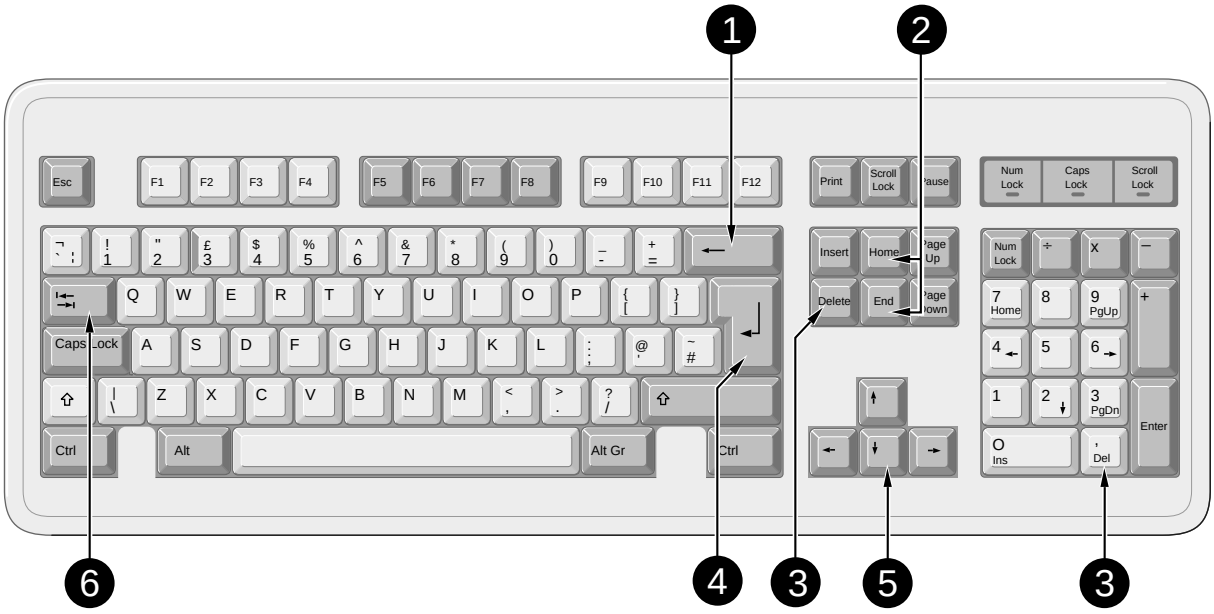


Figure 2-4. The keyboard

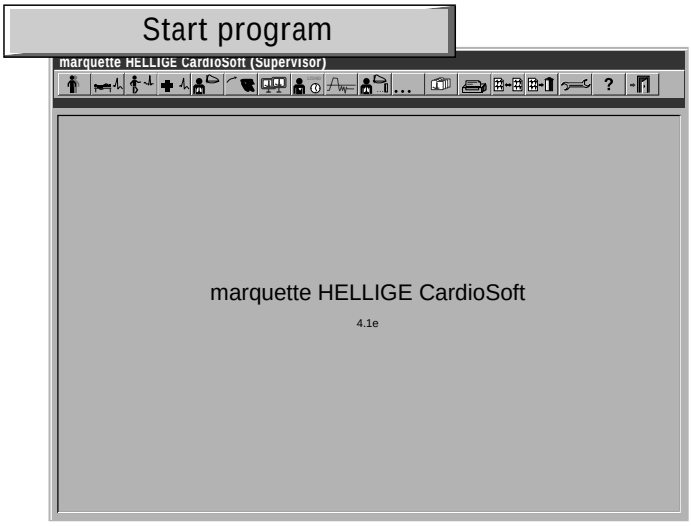


Figure 2-5. Title screen

> ***When the password function is enabled (section 6.1 "System Configuration –> General") enter the user name and password first.***

> ***The program may be configured to default to an operating mode, such as resting ECG. In this case you will see the patient selection screen instead of the title screen. Chapter 3 "Selecting and Admitting a Patient" explains how to retrieve a patient from the database.***

2.3 Starting the Program, Explanation of the Function Keys and Selecting the Language

Starting the Program

* Turn on the system and start the program by double-clicking on . The title screen (Figure 2-5) appears. When the password function is enabled in the System Configuration (tab "General"), you will see the user registration window.

Enter the name and password and click on the Start program button.

Explanation of the Function Keys

The function keys are used to call up the different program functions:

Opens a window for patient selection or for admission of a new patient (section 3.1, 3.2)

Recording of a resting ECG (section 4.1)

Recording of an exercise ECG (section 4.2)

Recording of a STAT ECG (section 4.3)

Initiates a pulmonary function test (section 4.4)

Initiates the ambulatory BP program for programming of the BP monitor and data evaluation (section 4.5)

Initiates the late potential analysis program (section 4.6)

Initiates a bronchodilation test (section 4.7)

Calls up further examination procedures

Opens a window for selection of stored procedures

Opens the printer menu and allows you to print the displayed procedure

Allows you to compare the current procedure with another one

Allows you to delete the displayed procedure

Calls up system services (chapter 6)

Calls up the online help function

Allows you to quit the program

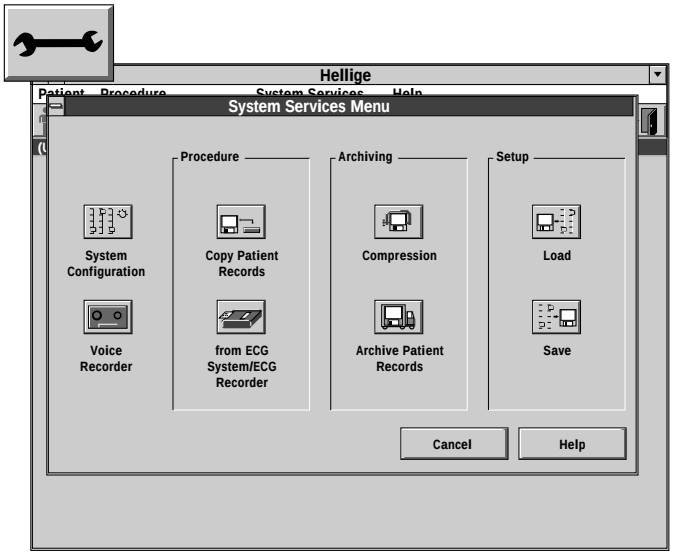


Figure 2-6. System services selection window

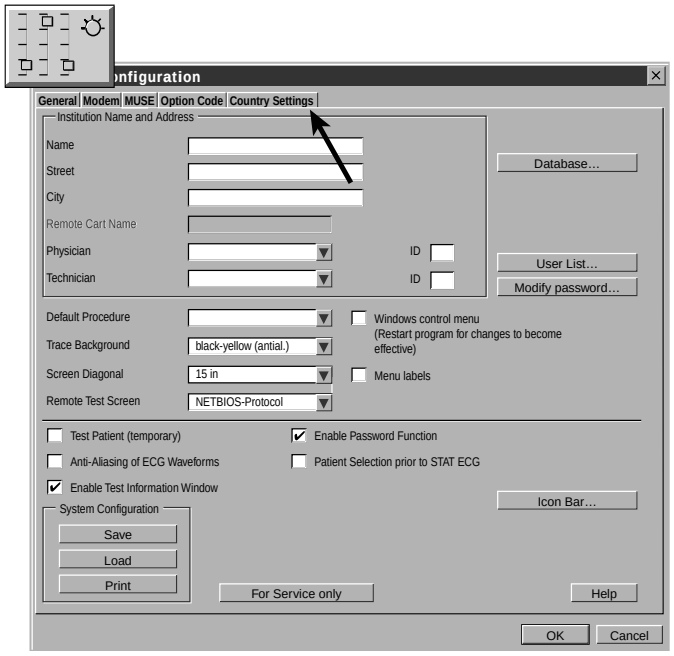


Figure 2-7. System configuration menu – "General" tab

Selecting the Language

The program offers different languages for the user interfaces and for the printed reports.

To select one of the languages, proceed as follows:

Click the button.

The window showing the system services opens (Figure 2-6).

Select .

You will see Figure 2-7. (This paragraph describes language selection only. Other settings to be made in this window are discussed in section 6.1)

Select the "Country Settings" tab (arrow, Figure 2-7).

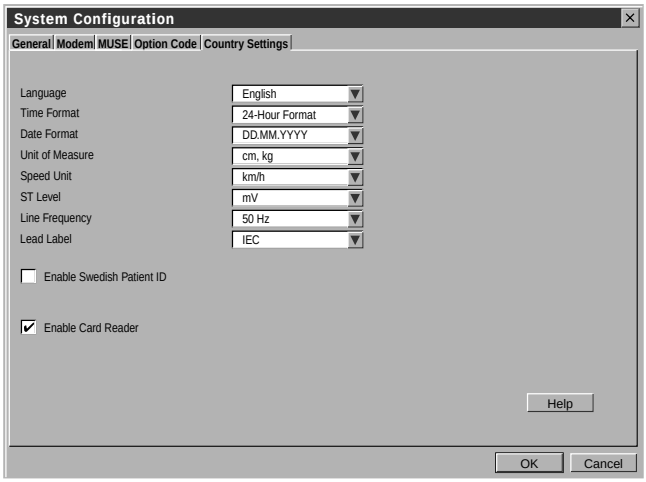


Figure 2-8. System configuration menu – "Country Settings" tab

A screen similar to Figure 2-8 appears.

Select your language from the "Language" list box and click OK to quit the menu.

For your notes

3. Selecting and Admitting a Patient, Retrieving Stored Examinations

In this section you will find information on

– how to select a patient from the database

– how to admit a new patient to the system

– how to retrieve examinations stored for a specific patient

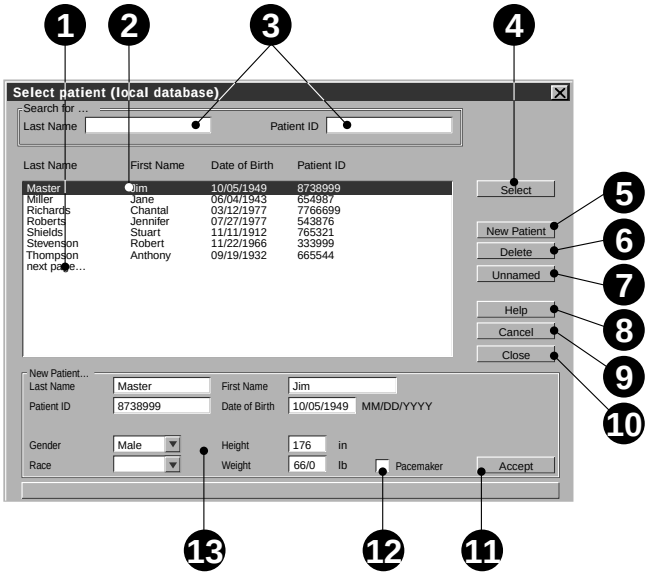


Figure 3-1. Patient selection screen

1 *Displays more patients*
2 *Bar cursor, highlighting selected patient*
3 *Text box for patient's last name*
4 *Click to select highlighted patient and go to the title screen*
5 *Click to enter new patient data*
6 *Clears the patient data*
7 *"Unnamed" button (the test will not be assigned to a patient)*
8 *Click to display the online help screen*
9 *Clears the menu (entries are not saved)*
10 *Displays the title screen*
11 *Click to save the data to the database*
12 *Pacemaker patient: yes* [x], *no* [ ]
13 *Patient data window*

> ***Depending on the system configuration you will be working with the local database or with the database of the MUSE CV system.***

3.1 Retrieving a Patient From the Database

An examination procedure can be assigned to a patient only when this patient has been retrieved from the database or when the patient is admitted to the system first. Similarly, you have to select a patient from the database before recalling one of the procedures stored for this patient ("Unnamed" allows you to run a procedure without assigning it to a patient).

Click on [ ] to display the patient selection screen.

Local Database (Figure 3-1)

Type the last name or ID number of the patient whose record you wish to retrieve (it is sufficient to enter the first letters or numbers).

Click at (1) to display a new page of patient records.

Check the patient data. If it needs to be changed:
– type over the old text, and
– click [Accept].

To select the highlighted patient record
– click [Select], or
– press [↵].

As an alternative, you can select a patient record by double-clicking on the name.

If you are working with the keyboard only;
- enter the patient name,
- press the → key twice, and
- confirm the selection with .

Selecting a Patient from the MUSE CV System Database

When working with the MUSE CV system database, remember the following limitations:

- it is not possible to search the database for a patient by the patient ID number
- patients can be admitted or deleted at the MUSE CV system database only
- patient data can be edited at the MUSE CV system database only

> ☞ ***Refer to chapter 6 for instructions on configuring the system for communication with the MUSE CV system database.***
> ***In a network environment, do not access the same patient file from more than one workstation.***
> ***Use only standard ASCII letters (A through Z) and numbers (0 through 9) when entering information for the MUSE CV system.***

Entering Patient ID with the Bar Code Wand

- Click on the “Patient ID” text box.
- Place the wand on the recording, at least 10 bars’ breadths to the left of the bar code.
- Tilting the wand moderately, drag it across the bar code at an even pace. If necessary, use a ruler as an aid.

> ☞ ***Do not activate the Shift Lock key on the keyboard when using the bar code wand.***

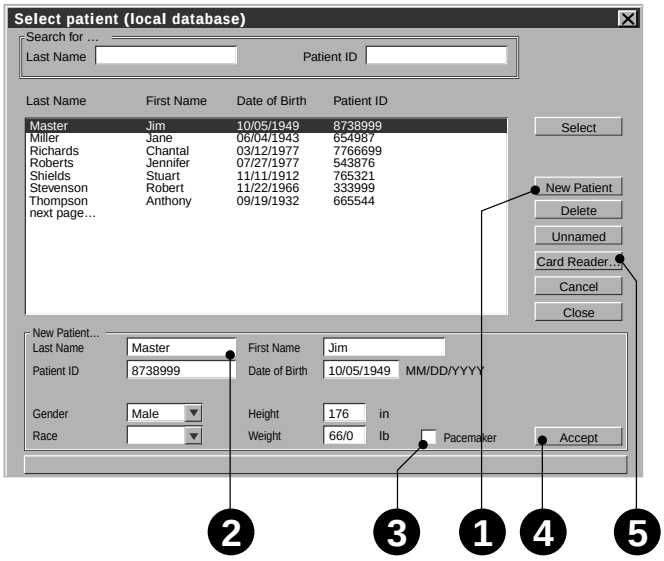


Figure 3-2. Patient data entry screen

1 *Click to enter new patient data*
2 *Text box for patient's last name*
3 *Pacemaker patient: yes* [x] *, no* [ ]
4 *Confirms the entered data*
5 *Click to enter patient data via card reader*

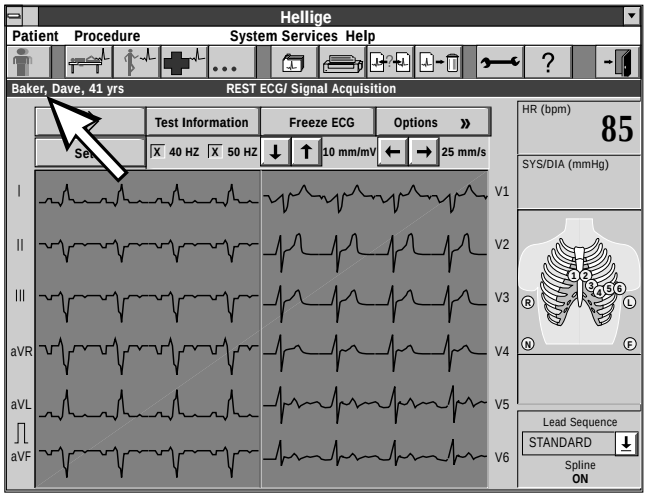


Figure 3-3. Headline with the selected patient's name

3.2 Admitting a New Patient

Click **New Patient** (1, Figure 3-2).

Enter the patient's last name, and press the → key to move to the next box, etc.

Use the spacebar to apply or remove the checkmark in the Pacemaker checkbox.

Click **Accept** to save the new patient file to the database (or press the → key and then the spacebar).

To admit a patient with the card reader click **Card Reader...** and follow the displayed instructions (the card reader function must be enabled in the System Configuration menu, but this function is not supported by all keyboards).

> ***The first letters of the first and last names are automatically capitalized. Enter only ASCII characters and numbers for the MUSE CV system.***

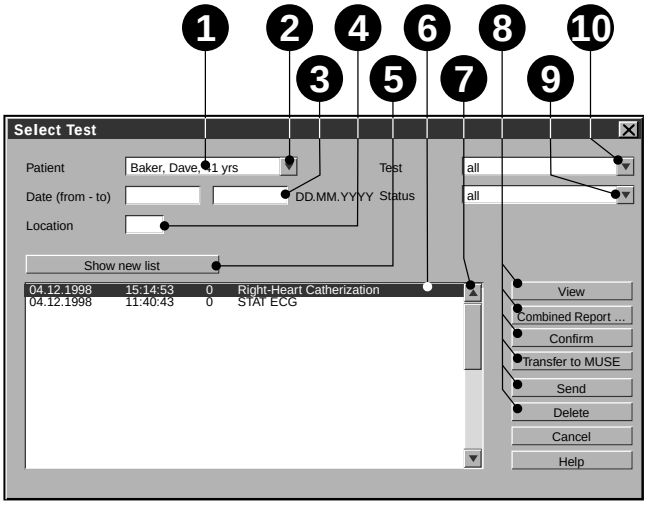


Figure 3-4. Window for selection of stored tests

1 *Selected patient (only this patient's records are displayed)*
2 *Choose "all" if you want to see all stored tests*
3 *Selection of the search filter (date range)*
4 *Selection of the search filter (tests recorded at a special location)*
5 *Displays list when all search filters were set*
6 *Selected test*
7 *Click arrow to scroll through list*
8 *Control buttons*
Displays the selected test
Displays a combined report
Allows the selected test to be confirmed
Saves the test for MUSE (to the database or storage medium, as configured)
Allows transmission of procedures
Clears a test
9 *Selection of the search filter (confirmed, unconfirmed or all tests)*
10 *Selection of the search filter (only resting ECGs, only STAT ECGs, only exercise tests)*

3.3 Editing Stored Tests

Tests stored in the database can be retrieved

– to be reviewed
– to be assessed
– to be transmitted
– for creation of a combined report
– to be deleted.

Selecting a Test

Before you are able to edit test data, you will have to select a test from the database. You can either display a list of all stored tests or of the tests stored for a specific patient.

Select the patient.

Click on .

A list appears showing all the examination procedures stored for the selected patient (Figure 3-4). If you wish to see all stored procedures,

Click on (2, Figure 3-4) and select "all".

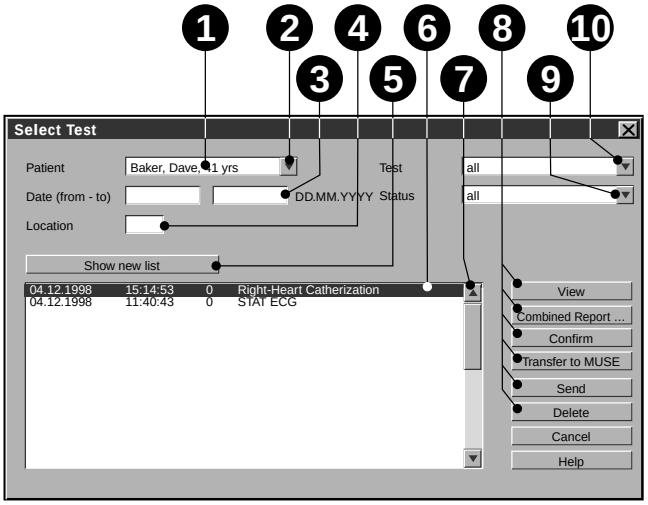


Figure 3-5. Window for selection of stored tests

1 *Selected patient (only this patient's records are displayed)*
2 *Choose "all" if you want to see all stored tests*
3 *Selection of the search filter (date range)*
4 *Selection of the search filter (tests recorded at a special location)*
5 *Displays list when all search filters were set*
6 *Selected test*
7 *Click arrow to scroll through list*
8 *Control buttons*
Displays the selected test
Displays a combined report
Allows the selected test to be confirmed
Saves the test for MUSE (to the database or storage medium, as configured)
Allows transmission of procedures
Clears a test
9 *Selection of the search filter (confirmed, unconfirmed or all tests)*
10 *Selection of the search filter (only resting ECGs, only STAT ECGs, only exercise tests)*

You can set various filters to display only those tests that meet specific criteria:

– test type (only resting ECG, only spirometry tests, only STAT ECGs (click ↓ (10, Figure 3-5), then select the test type)

– tests that were confirmed by a physician or unconfirmed tests (9, Figure 3-5). Confirmed tests are marked with an x.

– tests that were recorded at a special location (4, Figure 3-5). This could be an external ECG recorder or a particular test lab. Please refer to section 6.1 "System Configuration" for details on how to set the location number.

– tests that were recorded in a specific time range (3, Figure 3-5). Enter the beginning of the range in the box at left and the end in the box at right (click in the box first), observing the date format (DD.MM.YYYY or MM/DD/YYYY).

When you have set all filters, either press ↵ on the PC keyboard or click the Show new list button.

Tests marked with an asterisks are stored on an external storage medium. Follow the instructions displayed on the screen to restore these test data.

☞ ***You can select multiple procedures by clicking on the procedure and holding the Ctrl key depressed at the same time.***

☞ ***Double-clicking on a test is a quick method to select it from the database.***

☞ ***When working in a network environment, it is not possible to display the same test at more than one workstation at a time.***

☞ ***If multiple tests are highlighted when you first display the test records list, these are records that were sent from an ECG recorder and they may not be assigned to the correct patient, or a record was repeatedly sent and assigned to different patients.***

Displaying Tests

Select a test and clear the window with View.

The test report will be displayed. For details on the individual report documents, please refer to section 4.1.4.

Confirming Tests

A test is considered confirmed, when a physician has reviewed the test evaluation and "signed" it electronically with his/her name. It is possible to confirm tests more than once.

Select a test and clear the window with Confirm.

The screen automatically displays the report page with the interpretation statements. Please refer to section 4.1.4 for details on how to evaluate a test.

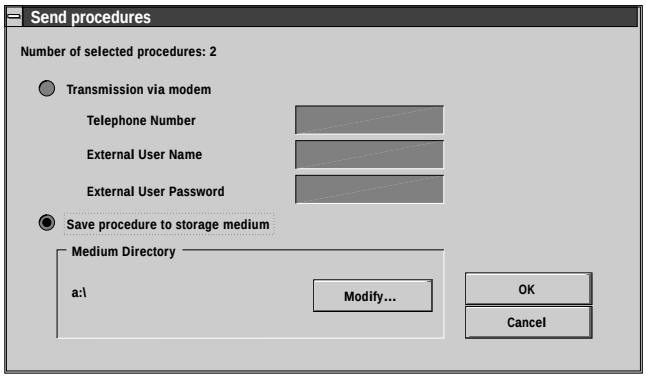


Figure 3-6. "Send procedures" window

☞ ***The addressee must be registered as "External user" at the receiving system (section 6.1 "System Configuration").***

☞ ***When sending data via the modem, please verify the modem settings (section 6.1 "System Configuration").***

☞ ***If the system cannot access the selected disk drive a:\, data will be saved to the hard drive c:\.***

Sending Procedure Data

You can transmit one or several procedures via a modem or save them to a storage medium.

Select the procedure(s) (multiple procedures can be highlighted by holding either ⇧ or Ctrl down when clicking on them).

Click on Send to clear the window.

Figure 3-6 will appear.

If you wish to send the data via modem, select "Transmission via modem" and enter the telephone number, name and password of the external user at the receiving end. Then select OK to clear the window.

If you wish to save the data to a storage medium, select "Save procedure to storage medium". Then select OK to clear the window.

You can change the directory by clicking on Modify...: a window opens showing the available directories.

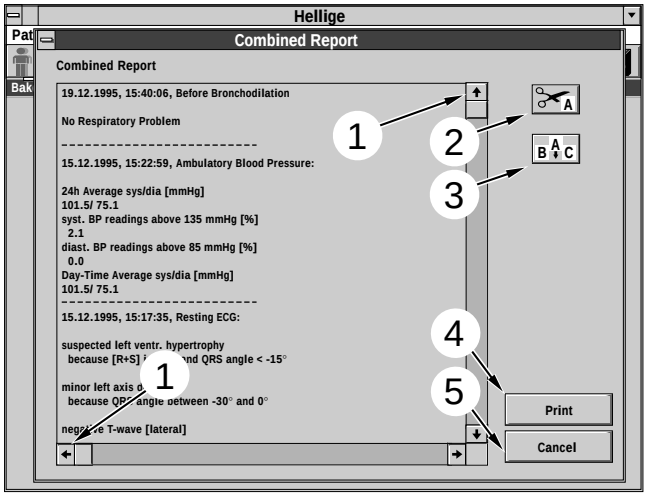


Figure 3-7. Combined report

1 *Arrow buttons and scroll boxes to reposition the text (up, down, right, left)*
2 *Button to delete text*
3 *Button to reinsert text*
4 *Button to initiate a printout of the combined report*
5 *Button to cancel the combined report*

Combined Report

You can select several tests of one patient, compile these in a combined report and print it out. This function is not available when the records of all patients are displayed.

- Select the patient.
- Select multiple tests by holding either ⇧ or Ctrl down when clicking on a test.
- Click on Combined Report.

Figure 3-7 shows an example of a combined report.

A combined report can be edited and printed, but it can not be saved.

- If you wish to add text, position the cursor at the appropriate position and click. Then type the text.
- If you wish to delete text, highlight it, then click on .
- Deleted text can be inserted in any desired position. To do so, place the mouse cursor at the appropriate point and click. Then click on .
- The arrow buttons and scroll boxes (1) can be used to reposition the text (up, down, right, left).
- The Print button is used to initiate the printout of the combined report.

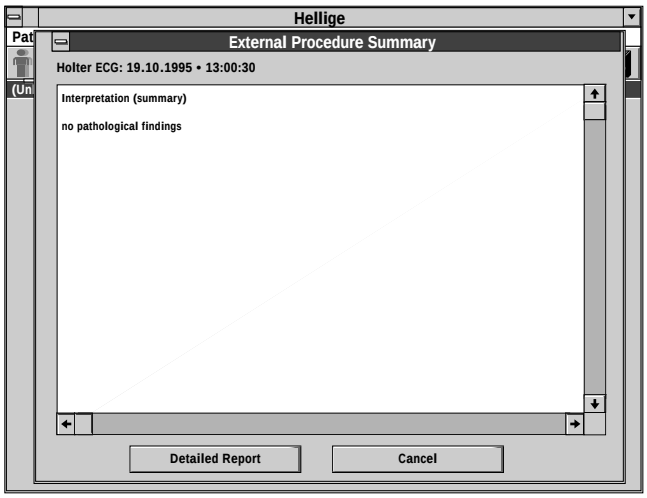


Figure 3-8. Summary

For examinations made with an external program, you will see a procedure summary (Figure 3-8), when you press the OK button.

Delete Stored Tests

The Delete button allows you to remove the highlighted test(s) from the database.

Sending Test Data to the MUSE CV System

Use only standard ASCII letters (A through Z) and numbers (0 through 9) when entering information for the MUSE CV system.

Once transferred to the MUSE CV system, the tests cannot be edited any more.

Data sent to MUSE can be viewed with the MUSE Browser and printed. Note: Before printing, always set the printer to the landscape format.

If you enable “Start modem connection before transfer” on the MUSE tab of the System Configuration menu, the system may still find an active modem connection while it tries to establish a new connection. Windows NT will inform you of this condition. Terminate the existing connection (Hangup) and resend the data.

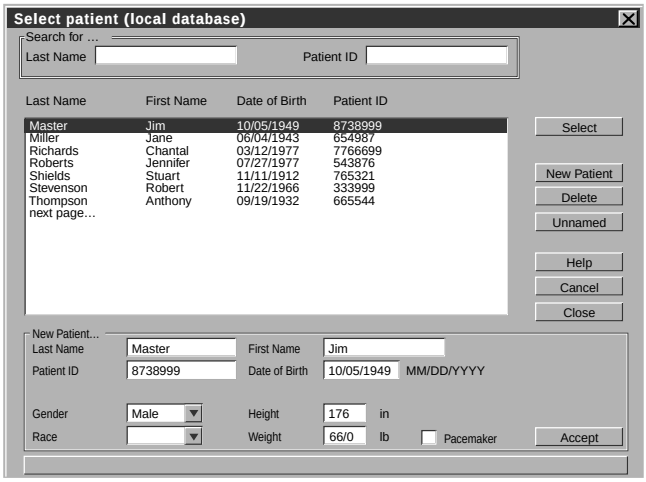


Figure 4.0-1. Patient selection screen

4. The Examination Procedures

The following sections describe the different examination procedures possible with CardioSys (resting ECGs, exercise tests, STAT ECGs, etc.) in detail.

When you click on one of the procedure selection buttons, the patient selection screen opens, allowing you to retrieve a patient from the database or to enter a new patient (sections 3.1 and 3.2). The advantage of this approach is that you can immediately select the examination procedure without having to choose a patient first.

On the patient selection screen the bar cursor is always on the patient selected last. So, if you wish to perform multiple tests on the same patient, all you have to do is click on the Select button or press ↵.
If you prefer to run an unassigned procedure, click on Unnamed.
Choose Close to display the title screen.

If you run the program in conjunction with a hospital information system (HIS), the Order List button will also appear, enabling you to display a list of requested procedures (this function requires the optional “Order List” module, refer to Appendix 2 “Operation in Conjunction with a Medical Reimbursement Program/Hospital Information System”).

For your notes

4.1 The Resting ECG

This section describes all operating steps necessary to

- apply the electrodes to the patient and connect the patient
- enter the test information (indication, medication, comments, etc.)
- record the ECG
- call up the report pages for on-screen review
- print the report pages
- compare two resting ECGs
- set up the system

The brief operating instructions at the end of this section sum up what you have to do to record a resting ECG.

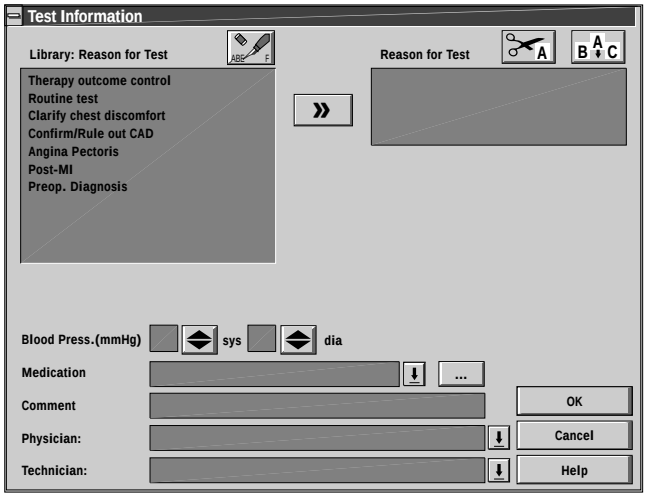


Figure 4.1-1. Test information window

4.1.1 The Basics

Choose the icon to activate the resting ECG mode.

After selection of a patient, the window for entry of the test information will open (Figure 4.1-1), if you have chosen this feature in the system configuration (refer to section 6.1 “System Configuration”). We recommend that you apply the electrodes to the patient as explained in section 4.1.2 prior to entering the test information.

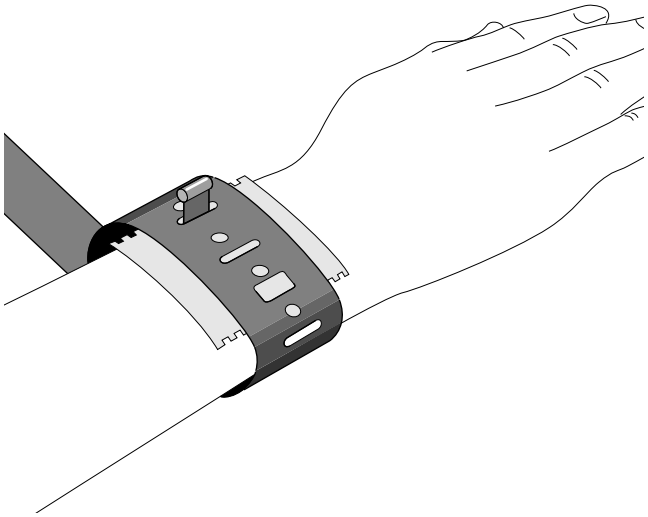


Figure 4.1-2. Applying plate electrodes

☞ ***The red R electrode is the reference electrode. Placement and signal quality of all other electrodes can be assessed on the signal acquisition screen only when this electrode is applied.***

4.1.2 Applying the Electrodes

Careful application of the electrodes is a prerequisite for obtaining interference-free ECGs. The signal acquisition screen immediately gives you a visual indication of your electrode technique and of the signal quality (provided the red R electrode is applied).

For quick, reliable and trouble-free application of the electrodes we recommend our Electrode Application System (refer to the Electrode Application System user manual).

As an alternative you can use the conventional plate electrodes on the limbs and the suction electrodes on the thorax.

Applying Plate Electrodes (Limbs)

Plate electrodes are applied by means of a rubber strap; electrode paper is the recommended contact medium for this type of electrode.

* Moisten the electrode paper with tap water and place it between skin and electrode.

* Secure the electrode with the rubber strap (Figure 4.1-2) so that it cannot shift during the recording; take care not to strangulate blood vessels in the process.

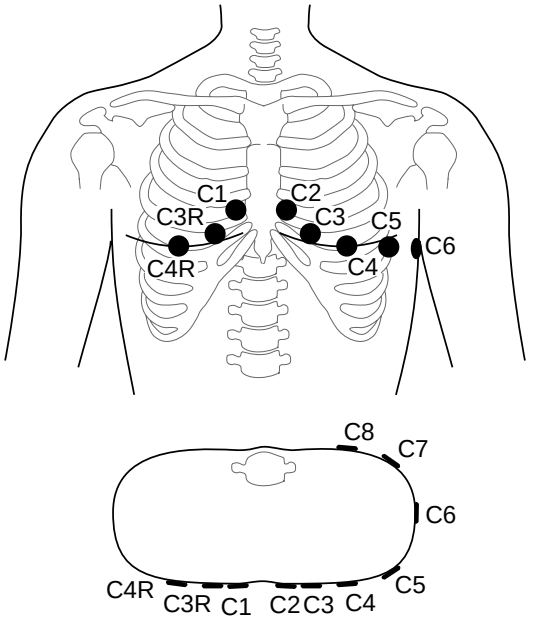


Figure 4.1-3. Chest electrode application points

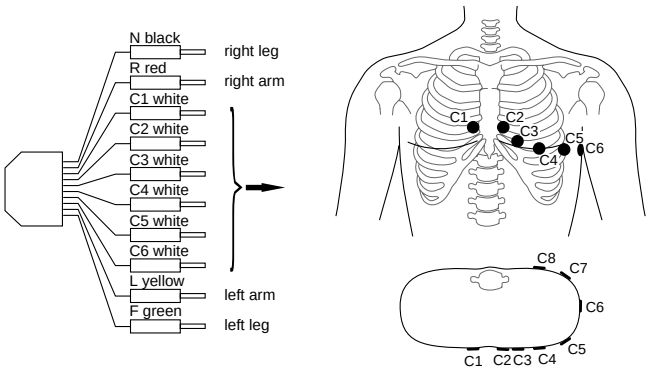


Figure 4.1-4. Connecting the patient cable (10-wire, standard ECG leads)

Applying Suction Electrodes (Thorax)

* Shave application points, if necessary.

* Moisten electrode paper with tap water and place it between skin and electrode. Electrode cream or gel can be used here instead of the paper. Especially when the chest is a little hairy, cream or gel helps to seal.

Electrode Application Points for Standard Leads (I, II, III, aVR, aVL, aVF, V1 to V6)

Four limb and six chest electrodes must be applied for acquisition of the standard leads. Attach the limb electrodes above the wrists and ankles. Figure 4.1-3 shows the chest lead application points:

C1 in the 4th intercostal space at the right sternal edge
C2 in the 4th intercostal space at the left sternal edge
C3 at the level of the 5th rib midway between C2 and C4
C4 in the 5th intercostal space on the left midclavicular line
C5 on the left anterior axillary line between C4 and C6
C6 on the mid-axillary line at the level of C4
C7 in the 5th intercostal space on the left posterior axillary line
C8 in the 5th intercostal space on the left scapulary line
C3R opposite C3, on the right side of the thorax
C4R opposite C4, on the right side of the thorax

* Connect the 10-wire patient cable as shown in Figure 4.1-4.

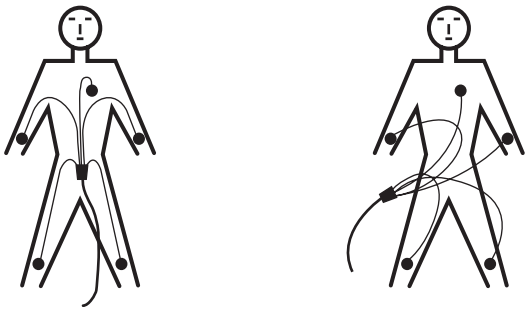


Figure 4.1-5. Arranging the patient cable

* Arrange the patient cable as shown in Figure 4.1-5 and connect it to the system (type CF signal input: highly isolated, suitable for intracardiac application, defibrillation-proof).

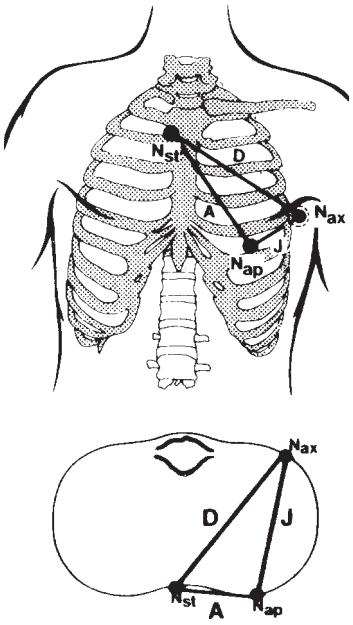


Figure 4.1-6. Electrode application points for NEHB leads

- N_{st} *attachment point of the 2nd rib to the right sternal edge*
- N_{ax} *in the 5th intercostal space on the left posterior axillary line (identical with C8)*
- N_{ap} *in the 5th intercostal space on the left mid-clavicular line (identical with C4)*

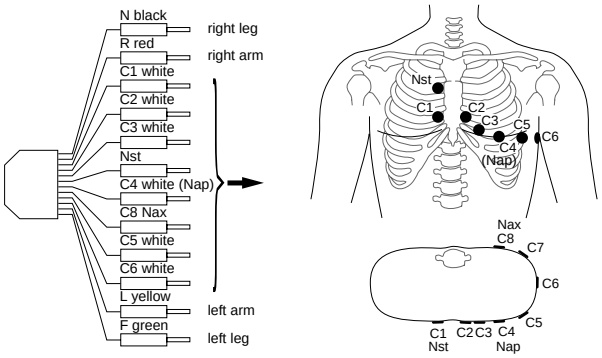


Figure 4.1-7. Connecting the patient cable (12-wire, NEHB leads)

Electrode Application Points for NEHB Leads

Figure 4.1-6 shows the application points for the NEHB electrodes. Connect the 12-wire patient cable as shown in Figure 4.1-7 (N_{ap} is identical with C4).

* If necessary disable the anti-drift system and the filters (muscle and AC line filter) to view the unfiltered "raw" ECG signal (sections 4.1.4 and 4.1.7).

As an alternative the NEHB leads can also be acquired with the 10-wire patient cable. In this case, select the sequence High, Right or Left as described in section 4.1.7 ("Modifying the Lead Sequence") and change:

I	to	D
II	to	A
III	to	J.

Apply the R electrode to Nst
the L electrode to Nax (C8)
the F electrode to Nap (C4).

☞ ***It is not possible to record chest leads at the same time as NEHB leads.***

☞ ***Please observe the information given in sections 7.1 "Artifact Due to Poor Electrode Application", 7.2 "ECGs of Pacemaker Patients" and 7.3 "ECG Recording During Defibrillation" in the appendix.***

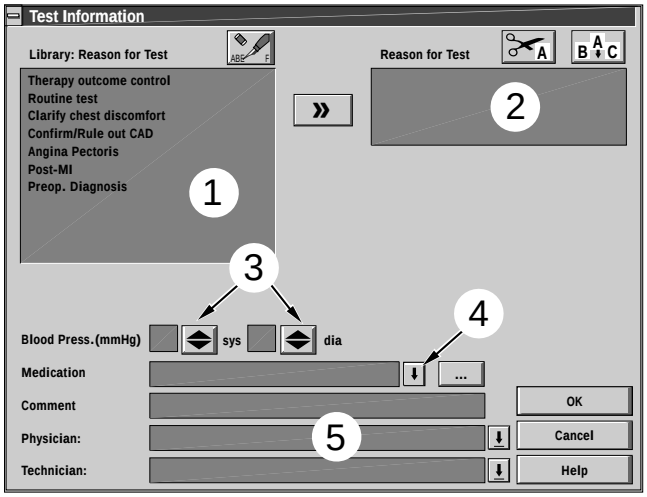


Figure 4.1-8. Test information screen

1 Reason for Test Library

2 The patient's reason for test

3 Blood pressure readings

4 Medications

5 Boxes for entry of comments and of the physician's and technician's names

4.1.3 Entering the Test Information

The test information screen offers menus and text boxes for entry of all data relevant for the resting ECG procedure.

On this screen you can

– enter the reason for the test

– enter blood pressure readings

– select the medication

– enter comments

– register the physician's and technician's names.

Copying Reason for Test from the Library to the Patient Window

The reason for test library contains a list of standard statements that you can copy easily into the patient's window. The library can be expanded or edited as required.

Click on a statement to highlight it.

Click the [>>] button.

A Reason for Test can easily be copied by double-clicking.

If you wish to delete a copied reason or part of it, highlight the words in question and click [✂A].

The deleted words can be inserted in another position by placing the cursor there and clicking [A B C].

You can enter a reason for test directly by moving the cursor to the desired position and typing the text.

Expanding or Editing the Reason for Test Library

Click [ABE F].

This will open the library window (Figure 4.1-9).

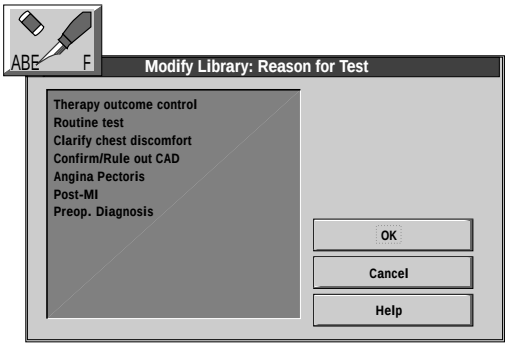


Figure 4.1-9. Editing the Reason for Test library

Move the cursor to the desired position in the list and click the mouse button.

Enter a standard statement and press [↵] on the keyboard. The cursor moves to the beginning of the next line.

In this manner you may enter all reasons for a test . When you're done, click on OK to clear the window.

Entering Blood Pressure Readings

Click ▲ to display and increase the value, or click ▼ to decrease the value.

Blood pressure readings are either entered directly via the keyboard or they are selected and changed in steps of 5 mmHg by clicking the arrow boxes. When you first click the arrows you will see default pressures of 120 mmHg (sys) and 80 mmHg (dia).

Move the cursor to the sys box and click the left mouse button.

Enter the value via the keyboard.

Enter the diastolic value in the same manner.

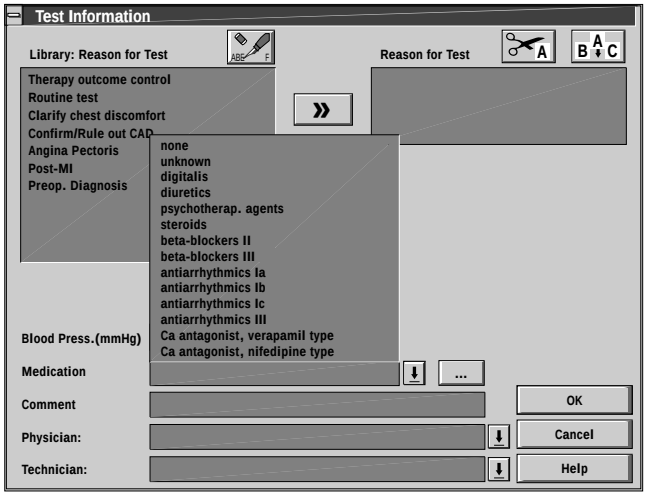


Figure 4.1-10. List of medication groups

> ***The physician is responsible for assigning drugs to a medication group.***

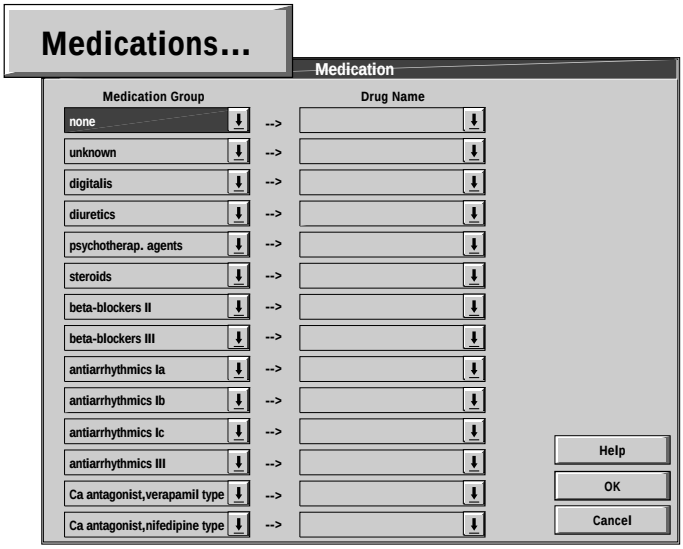


Figure 4.1-11. Assigning a drug to a medication group

Selecting a Medication, Assigning a Drug Name to a - Medication Group

You can select a medication from a list of 14 items [↓]. You can also select a second medication and assign specific drugs to the medication groups to include these in the list instead of the group name [...].

Making a Selection

Click on [↓] to open the medication list box (Figure 4.1-10).

Select one of the medications.

If you wish to select a second medication or to assign a drug name to a medication group, click on [...] and select the medication as described above.

Assigning Drugs to a Medication Group

Click on [Medications...].

A window opens, showing 14 items (Figure 4.1-11). There is a drug name window for each of these groups. Click on the respective text box, if you wish to enter a name. Then type the drug name.

Furthermore, you are free to arrange the medication groups any way you want. To do so

Click on the [↓] at the end of the group name box.

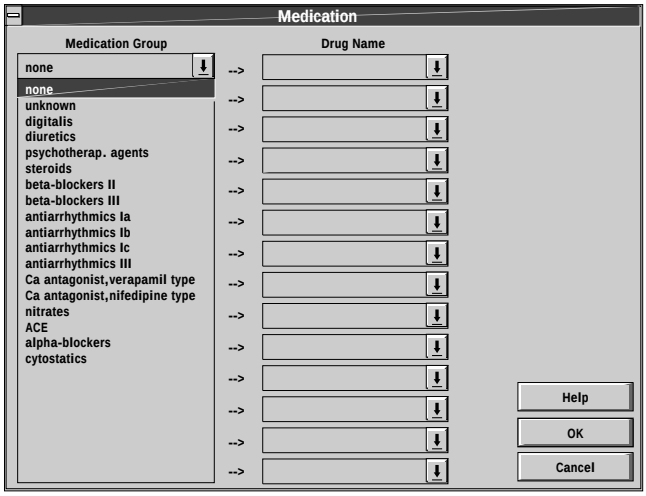


Figure 4.1-12. Editing the medication group

Pressing the ↵ key on the PC keyboard also clears the window and saves the entries.

This brings up a new window where you can choose one of the group names (Figure 4.1-12).

Click on the drug name box and enter the name

Click on OK to clear the window.

Entering Comments

If you wish to enter a comment on the test procedure, click in the “Comment” text box and key in the text.

Physician’s/Technician’s Name

The names of the physician and ECG technician can either be entered here (click in the text box and type the name), or they can be selected from the list of the registered system users (section 6.1 “System Configuration”).

Click on ↓ and choose a name from the list by clicking on it.

Exiting the Test Information Screen

Once you have entered all test information, you can either

– clear the window with OK and start recording the resting ECG or

– clear the window with Cancel (in this case the test information will be ignored and are not assigned to the test)

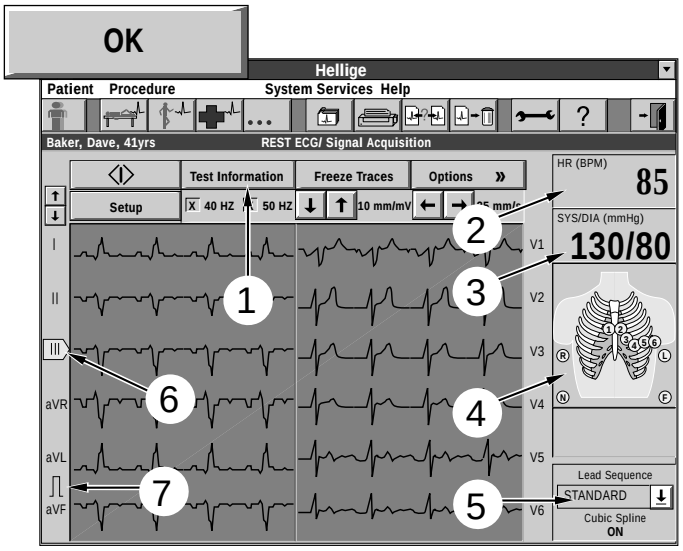


Figure 4.1-13. Signal acquisition screen for the resting ECG

1 Control buttons
2 Current heart rate
3 Blood pressure readings
4 Applied electrodes
green: properly applied
yellow: not properly applied
white: site not used
red: electrode off or lead break
5 For selection of the lead sequence
6 Leads impaired by poor signal quality
7 Calibration pulse

☞ ***The applied electrodes are shown on the torso only for the "Standard" and "CABRERA" lead sequences. In all other cases there is only a schematic representation of the electrodes. The reference electrode R (red) must be applied for the lead-check function to work properly.***

4.1.4 Recording A Resting ECG

Once you have entered the test information and cleared the window with OK, the signal acquisition screen for the resting ECG (Figure 4.1-13) will appear. Take a few seconds to become familiar with the details shown on this screen before proceeding to recording the resting ECG.

The resting ECG signal acquisition screen

This screen (Figure 4.1-13) shows:

– the current heart rate (2) and the blood pressure readings (3) (if entered manually, section 4.1.3)

– the applied electrodes and the signal quality (4). Furthermore an arrow (6) points to the leads which are impaired by improper electrode application or which cannot be recorded due to disconnected electrodes (or due to a break in the patient cable).

– the selected lead sequence (5)

– the selected sensitivity (the 1-mV calibration pulse (7) is valid for all channels).

This program allows you to select specific system settings similar to a conventional ECG recorder. You can enable or disable muscle and AC line filters, select different sweep speeds and sensitivities, etc. Furthermore, you can set up the system to suit your personal needs and preferences. These settings will be retained and are activated each time the system is turned on (section 4.1.7 "Setup").

> ***Settings selected from the Setup menu will be retained and are automatically activated each time the system is turned on.***

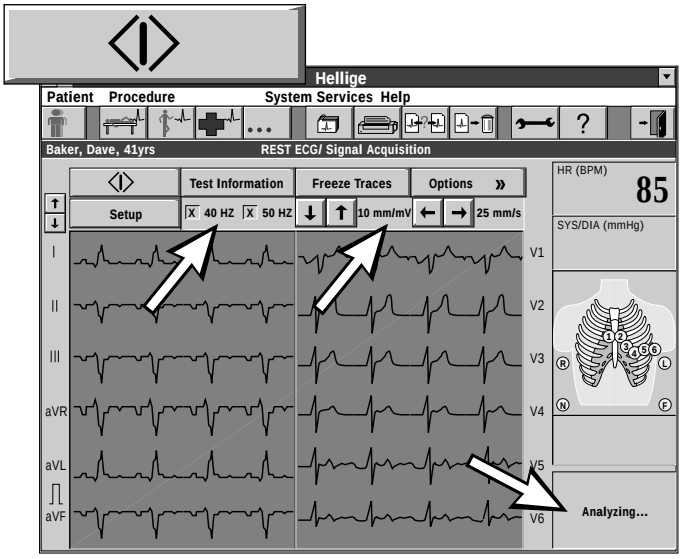


Figure 4.1-14. Resting ECG acquisition screen with control buttons and "Analyzing..." message

> ***Please remember that a filter may also suppress diagnostically relevant information, as it limits the frequency bandwidth. Therefore you should not switch filters on indiscriminately.***

> ***If "Manual Override" is enabled in the Setup menu (section 4.1.7), the system starts recording the ECG even when not all electrodes are applied.***

Click [Options >>] to display the system settings buttons.

Select [Setup] to display the setup menu (section 4.1.7).

The buttons [↑] and [↓] allow you to change the display of the ECG leads: either you see 5-second segments of all 12 leads at a time, or you see 10-second segments of groups of 6 leads.

The 40 Hz box switches a muscle filter on and off

The 50 Hz check box switches an AC filter on and off ([x] = AC filter on).

The arrows at [↑] [↓] mm/mV select the gain (2.5, 5, 10, 20, 40 mm/mV).

The arrows at ... mm/s select the sweep speed (25 or 50 mm/s).

The entire ECG recording is controlled with the four buttons:

[◇|◇] [Test Information] [Freeze Traces] [Options >>].

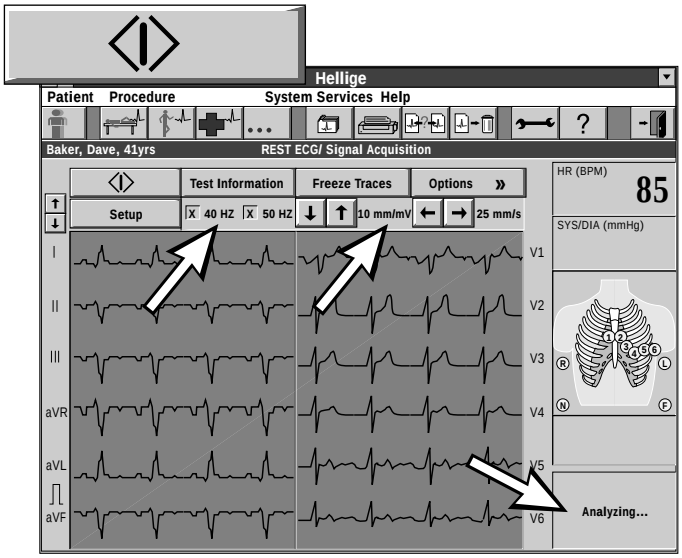


Figure 4.1-14. Resting ECG acquisition screen with control buttons and "Analyzing..." message

Recording and Evaluating the ECG

The program continually saves 10-second segments of the incoming ECG. When you click the button, the most recent 10 seconds of the ECG signal will be analyzed. Thus, before initiating the analysis, you can make sure that the quality of the ECG signal to be evaluated is adequate.

If you wish to modify the sweep speed or the filter settings (muscle, AC line filter), click on to display the second row of controls.

Click to freeze and release the signal traces. The freeze function does not affect channel 1.

Click to initiate the procedure. The message "Analyzing..." which appears in the bottom right-hand corner for about 6 seconds tells you that the signal is being analyzed (Figure 4.1-14).

At the end of the analysis you will automatically see the first page of the procedure report showing the 10-second ECG strips (Figure 4.1-15).

The resting ECG report includes the following documents which are described in detail on the following pages:

– the ECG traces (Figure 4.1-15/4.1-16)
– the test summary (Figure 4.1-20)
– medians (dominant, subdominant) (Figure 4.1-22)
– arrhythmia review (Figure 4.1-25)
– interpretation (Figure 4.1-27)

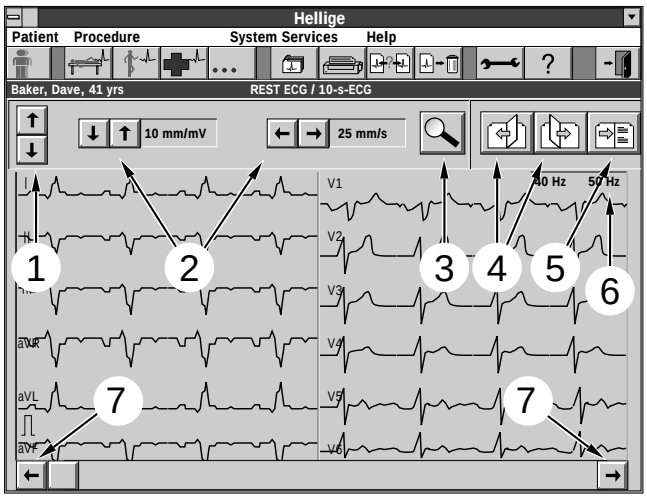


Figure 4.1-15. ECG trace display (2 x 6 leads)

1 Button to call up the optional 6-lead display (2 screens)

2 Buttons to change the gain and sweep speed

3 Button to zoom the ECG

4 Buttons to call up the other report pages (scrolling page by page)

5 Button to directly access specific pages

6 Procedure parameters

7 Buttons to display other time intervals

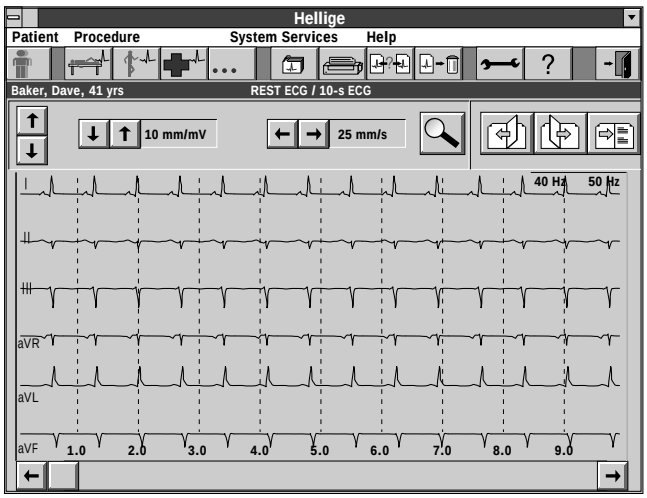

Hellige
Patient Procedure System Services Help
Baker, Dave, 41 yrs REST ECG / 10-s ECG
10 mm/mV
25 mm/s
40 Hz 50 Hz
1.0 2.0 3.0 4.0 5.0 6.0 7.0 8.0 9.0

Figure 4.1-16. ECG display, 6 leads/screen

ECG Trace Display

You can choose among three different formats for presentation of the ECG:

– 2 x 6 leads (Figure 4.1-15)
– 1 x 6 leads (Figure 4.1-16)
– 3 x 4 leads

Depending on the selected format and sweep speed the entire ECG (10 seconds) may take up several screens. The default format is the presentation of all 12 leads (Figure 4.1-15). Measurements can be performed on all ECGs (amplitude/ intervals/slope) (refer to the next section entitled “Zooming and Measuring the ECG”).

Click → (forward) or ← (backward) (7) to display another time window.

Click ↑ (2) to select another signal size.

Click → and ← (2) to select another sweep speed.

Click ↑ and ↓ (1) to display the 6 leads/screen format (Figure 4.1-16).

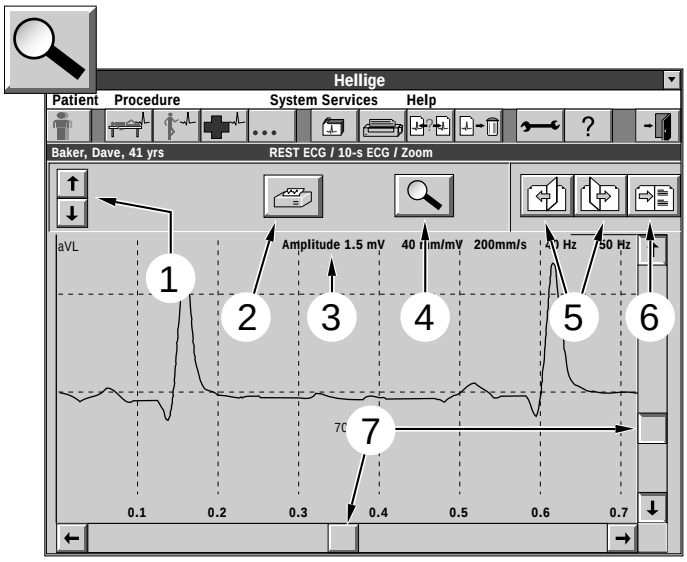


Figure 4.1-17. Zooming the ECG

1 *Buttons to display the same segment in another channel*
2 *Button to obtain a hardcopy of the displayed screen*
3 *Measured amplitude*
4 *Button to quit the zoom display*
5 *Buttons to display the other report pages (scrolling page by page)*
6 *Button to directly access specific pages*
7 *Scroll box to move the trace segment*

Zooming and Measuring the ECG

Zooming

The zoom function allows you to display a portion of the ECG at a larger scale.

Click .

Move the cursor to the region of interest that you want to zoom, and click. Your display looks similar to the one shown on Figure 4.1-17.

Click to display the same time window in another lead. The label of the selected lead is shown below the arrow buttons (Figure 4.1-17).

Drag the scroll box 7 (Figure 4.1-17) along the scroll bar to displace the trace segment vertically and horizontally.

To obtain a true-to-scale hardcopy of the displayed screen, click on the icon (the hardcopy includes the caliper marks).

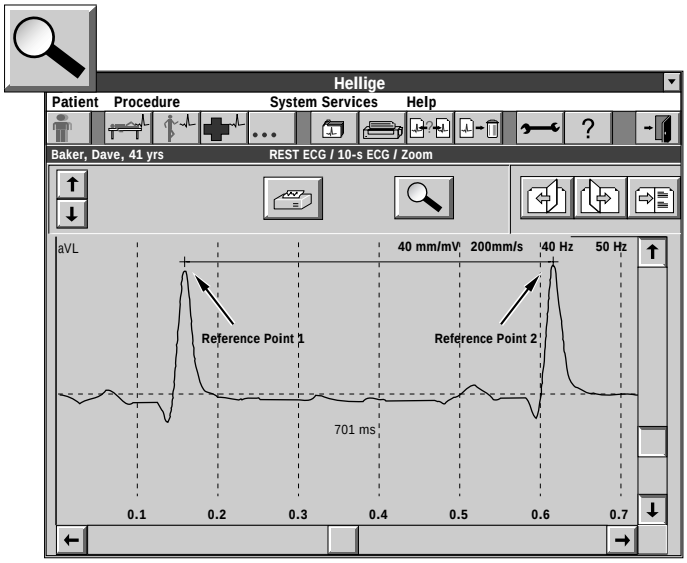


Figure 4.1-18. ECG measurement

Measuring the ECG

On all zoomed ECG displays you can measure amplitudes (mV), intervals (ms) and slopes (mV/s).

- As soon as you place the cursor in the ECG area, it becomes a caliper.

- Position the cursor on the first reference point and click. A green caliper now marks reference point 1. Then position the cursor on the second reference point and click again. A yellow line connecting these two points appears along with the measured value (Figure 4.1-18). The result is given in mV for the amplitude, in ms for the time interval, and in mV/s for the slope.

- Click the right mouse button to delete a reference point or an entire measurement.

On the zoomed display the position of the cursor is continuously indicated in mV at 3 (Figure 4.1-17), measured from the grid line at the center.

- Click to cancel the zoom display. The original display reappears.

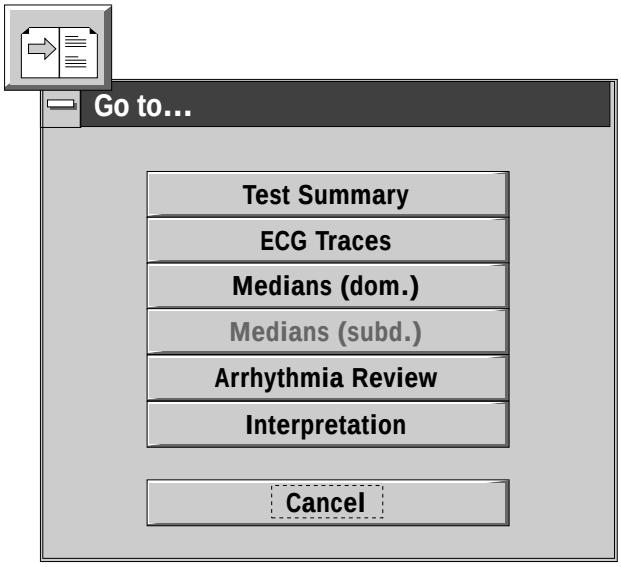


Figure 4.1-19. Table of contents of the resting ECG report

Displaying Other ECG Report Pages

You can either scroll through all ECG report pages, or access specific pages directly.

- Click to scroll forward or to scroll backward through the report.

- Click to display the table of contents from which you can choose specific report documents for review (Figure 4.1-19).

- Select the desired document by clicking.

The key functions described above are available for all documents. An explanation of the report pages follows on the next few pages.

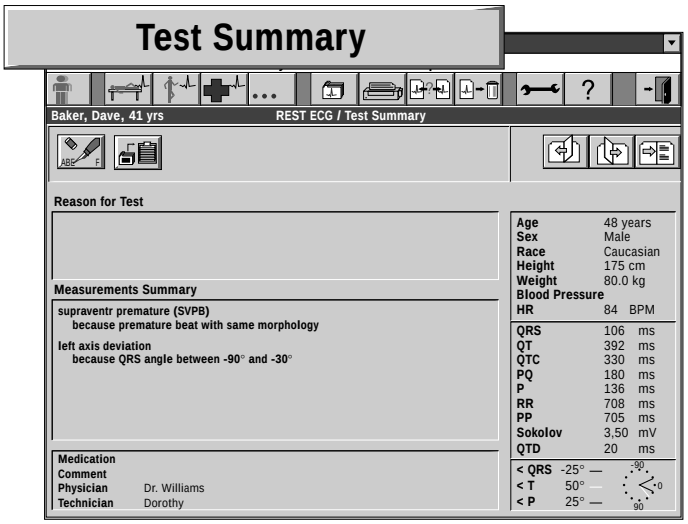


Figure 4.1-20. Test Summary

The Test Summary

The test summary (Figure 4.1-20) provides a survey of

Reason for Test (from the test information)

Measurements Summary (excerpt from interpretation, Figure 4.1-27)

Medication/Comment/Physician/Technician (from the test information)

Patient Data

Blood Pressure (from the test information)

QRS, QT, QTC, PQ, RR, PP interval (from the “Measurements”)

SOKOLOV LYON index: S (V1) + R (V5) or S (V1) + R (V6), whichever is greater (from the “Measurements”)

QTD (QT dispersion): max. difference between max. QT duration and min. QT duration of all leads

Vector angles

QRS, T and P angle (from the “Measurements”)

If you wish to add or edit procedure data, click on . Changing the medication will cause the program to reanalyze the ECG.

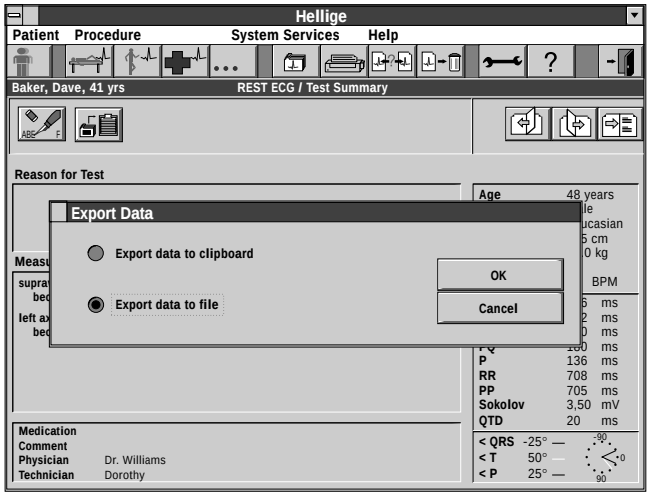


Figure 4.1-21. Data Export window

Data Export

The icon allows you to export the most important data pertaining to the resting ECG procedure to the clipboard or to any file. Data exported to the clipboard, for instance, can be inserted in a text file with the “Edit” —> “Paste” command.

Click .

Select either “Export data to clipboard” or “Export data to file”.

Click on OK.

Data from the clipboard can be imported in a word processing program with the “Paste” command.

For data exported to a file you will have to specify the target directory and confirm it with OK.

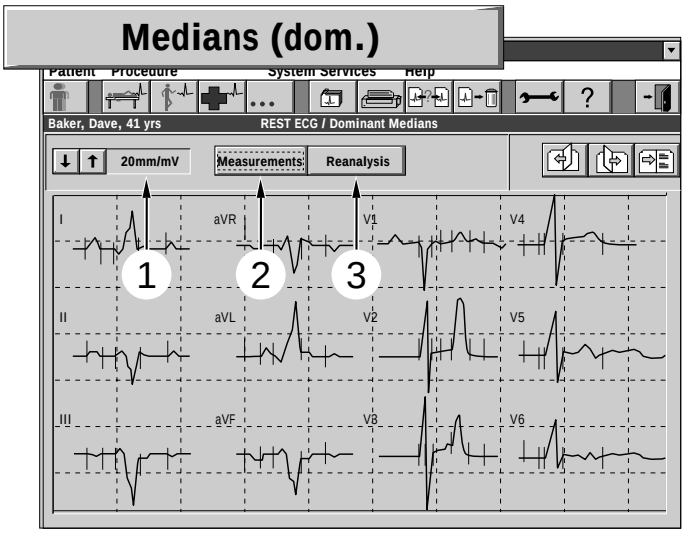


Figure 4.1-22. Medians

1 Button to change the signal size

2 Button to display the measured values

3 Button to display the re-analysis screen

Medians (dominant/subdominant)

The dominant (and, if present, the subdominant) medians of all leads are displayed together on one screen (Figure 4.1-22). The reference marks are shown as well. You are free to perform additional measurements as on the zoom display.

With the ↑ ↓ buttons you can change the signal size (default: 20 mm/mV).

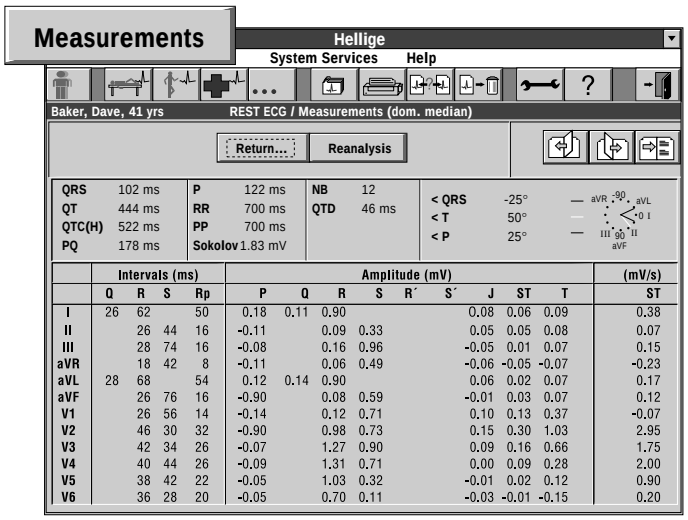


Figure 4.1-23. Measurements (results obtained with the HEART measurement program)

Click **Measurements** to display the measured values (Figure 4.1-23).

Click **Reanalysis** to display a screen which allows you to adapt the analysis criteria to your needs (Figure 4.1-23).

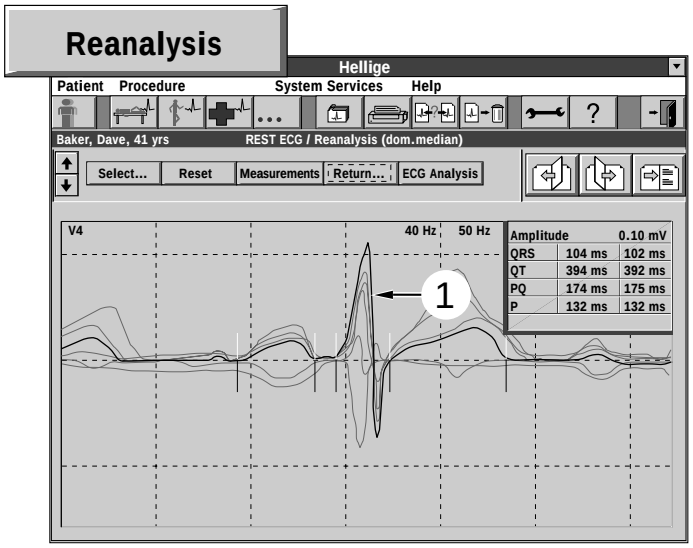


Figure 4.1-24. The reanalysis screen

1 active lead (highlighted)

> ***If the program was unable to locate the beginning and end of the P wave (e.g. in the presence of atrial fibrillation), the reference marks will be dashed. In this case the user can click on them with the right mouse button and drag them to the appropriate position. The user-selected marks are solid instead of dashed. It is possible to restore the original position of the reference marks by double-clicking on them.***

Reanalysis (HEART ECG Measurement Program)

Click [Reanalysis] to call up the reanalysis screen (Figure 4.1-24).

Here you see the medians of all leads superimposed. The reference marks determined by the system are located below the ECG baseline, those above the baseline can be moved with the mouse. A table in the top right-hand corner lists the time intervals.

You can perform the same measurements as on the zoomed display (amplitudes, intervals, slopes). The amplitude of the cursor position is continuously displayed in the top line of the table.

For a reanalysis of the ECG you can change the following settings:

– You select the leads from which the average beats for determination of the measurement marks are to be derived and which are superimposed ([Select...]).

– From these leads you choose one whose median complex is to be highlighted (buttons [↑] und [↓]).

– You move the reference marks above the baseline to any desired position (mouse).

– You perform a reanalysis ([ECG Analysis]).

– You cancel the reanalysis results ([Reset]).

First select the leads from which you want to derive the median complex for determination of the reference marks. Only those beats will be superimposed.

- Click [Select...]. A window opens showing all leads.
- Select the leads (check mark = lead is selected).
- Click [OK] to clear the window.
- Click the arrow button [↑] or [↓] to select the lead to be highlighted (1, Figure 4.1-24).

The measurement marks can be moved as follows:

- Position the cursor on the mark to be moved (above the baseline).
- Click the mark and, holding the mouse button depressed, drag it to its new position. Now release the mouse button. The time interval is updated in the table.
- When all marks are in the correct position, click [ECG Analysis] for a reanalysis of the ECG.
- Click [Reset] and then [ECG Analysis], if you wish to restore the original analysis results.

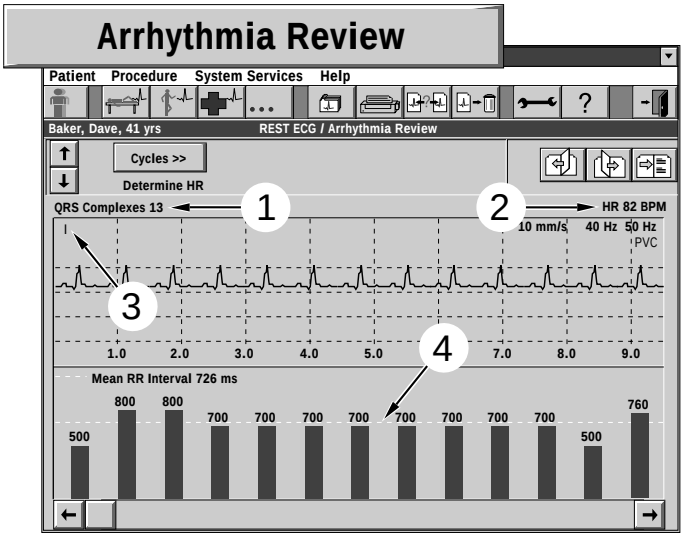


Figure 4.1-25. Arrhythmia review

1 number of identified QRS complexes
2 HR
3 displayed lead
4 mean RR interval

Arrhythmia Review

On the arrhythmia review screen (Figure 4.1-25) you see a 10-second segment of one lead at a time, including the identified events, such as PVC or PSVC.

A bar diagram below the signal trace indicates the deviation of the RR interval from the mean RR interval.

When first called up, the display shows the lead that you selected in the configuration menu. All other leads can be selected with the arrow buttons ↑ and ↓.

Furthermore you can determine the heart rate.

Measuring the Heart Rate in a Normal ECG

Click on the QRS complex at the beginning of the interval to be measured; the system automatically positions the cursor in the correct place.

Click on the QRS complex at the end of the interval. A line marks the measured interval and the resulting heart rate is displayed.

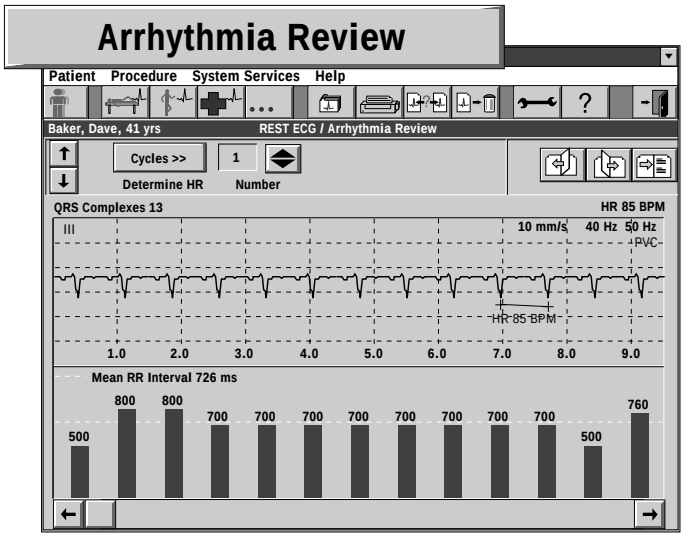


Figure 4.1-26. Calculating the heart rate

Measuring the Heart Rate in the Presence of Atrial Fibrillation or Flutter

In this situation you will have to define a cardiac cycle yourself.

Click Cycles >>.

A window opens where you can enter the number of cycles over which you want to measure the heart rate.

Click ◆ above Number to adjust the number of cycles.

Position the cursor at the beginning of the interval to be measured and click.

Count the number of cardiac cycles, position the cursor at the end of the interval and click again. The interval is marked with a yellow line and the heart rate for this interval is displayed (Figure 4.1-26).

Click the right mouse button to delete a single reference point or an entire measurement.

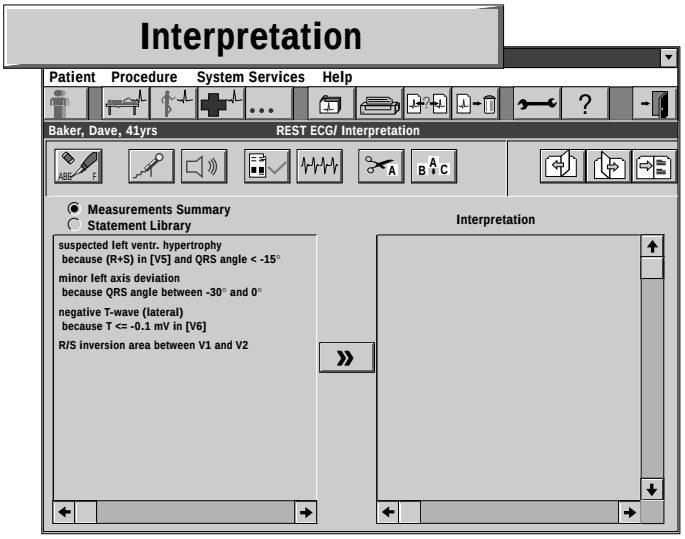

Interpretation
Patient Procedure System Services Help
Baker, Dave, 41yrs
REST ECG/ Interpretation
Measurements Summary
Statement Library
Interpretation
suspected left ventr. hypertrophy
because (R+S) in [V5] and QRS angle < -15°
minor left axis deviation
because QRS angle between -30° and 0°
negative T-wave (lateral)
because T <= -0.1 mV in [V6]
R/S inversion area between V1 and V2

Figure 4.1-27. Interpretation screen

You can copy individual lines by double-clicking.

Interpretation

The interpretation screen is split into two windows. The one on the left shows the interpretation as derived by the system or the library of interpretative statements, while the one on the right is reserved for the physician's interpretation. The physician's interpretation has priority over the system interpretation (for printing or in the procedure summary). Only when the procedure is assigned to a patient can the physician's interpretation be entered.

When writing the physician's interpretation you can first of all choose between the interpretation from the analysis program and the statement library, then you can copy parts or all of these statements to the right window. In the window at the right you can edit these statements again, using the icon to cut text and the icon to reinsert the text in any other place. You may also add any comments. Furthermore, you can record a spoken comment, using the icon, provided that a sound card has been implemented in your system and that you have a microphone. This comment will be saved to the corresponding patient file. It can be played back by clicking the icon.

The interpretation is shown to be confirmed only after it was signed by a physician ( ).

- First select the information to be displayed: the program measurements or the statement library (Figure 4.1-27).
- If you wish to copy phrases to the right, highlight the respective passages, then click .
- To enter text directly into the window on the right, move the cursor to the desired position, click the mouse button and type the text.

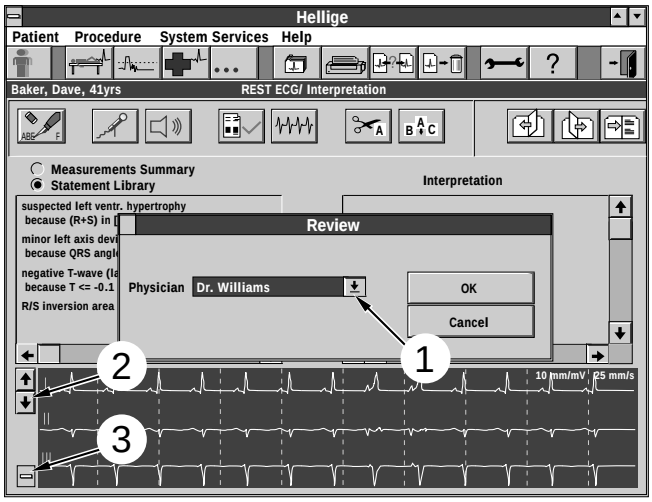


Figure 4.1-28. Interpretation screen with confirmation window and ECG

1 Displays the list of registered physicians

2 Displays the other ECG leads

3 Removes the ECG leads

Confirming an Interpretation

The interpretation of a recorded ECG is confirmed only after it has been reviewed and electronically signed by a physician (marked with a “X” in the procedure list).

Click on (Figure 4.1-28) to display the window for entry of the physician’s name.

Select the name from the list (open the list box with) or enter a name via the keyboard.

Editing the Statement Library

The icon becomes active as soon as you display the statement library (1, Figure 4.1-27).

Click on to open the window for entry of interpretative statements.

Key in new text or edit the existing phrases.

Select OK to clear the window.

Adding the ECG Waveforms

The icon can be used to display the ECG waveforms in the bottom half of the interpretation screen (Figure 4.1-28). Three leads are always displayed at a time. The other leads can be viewed with (2, Figure 4.1-28). Click on or to clear the ECGs.

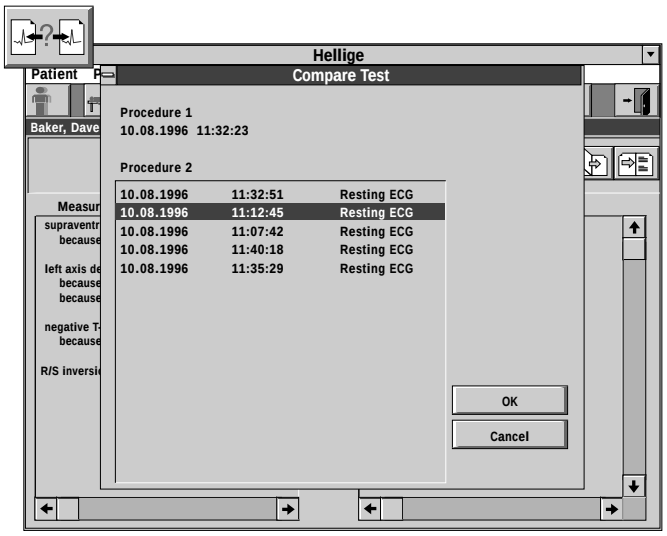


Figure 4.1-29. Window for selection of a resting ECG

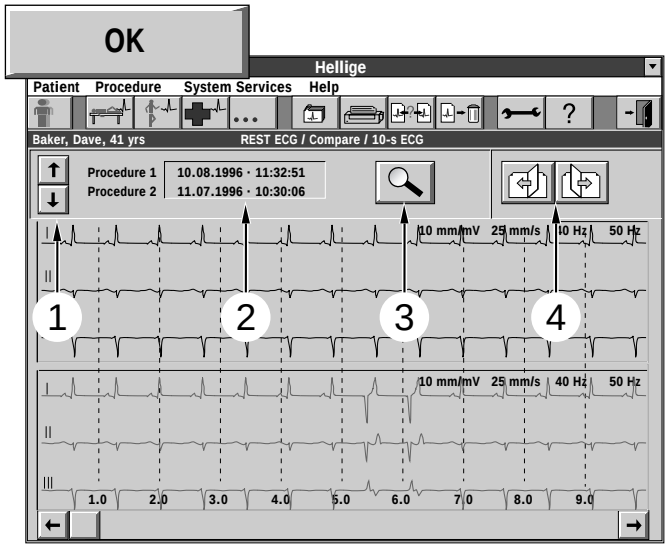


Figure 4.1-30. Comparing two resting ECGs

1 *Buttons to select the ECG leads*
2 *Procedure dates and times*
3 *Zoom button to display an enlarged ECG segment (both traces superimposed)*
4 *Buttons to display the medians*

4.1.5 Comparing Resting ECGs

You can compare the following details of two resting ECGs

– the 10-second ECG
– the median complexes (dominant and sub-dominant)
– the interpretation

At the same time it is possible to compare the median complexes of at least 3 and up to 6 ECGs.

Comparing Two Resting ECG

The system offers you to compare the present resting ECG with another one stored in the database.

For the example below we assume that you wish to compare the recent ECG with an earlier recording of the patient. Of course, you are free to call up any ECG (section 3.3 “Editing Stored Examinations”) and compare it with any other ECG as described below:

Click .

A window will open listing all of the patient’s resting ECGs (Figure 4.1-29).

Select a recording and click OK to clear the window.

The comparison screen appears (Figure 4.1-30).

It is possible to select multiple ECGs at the same time. To do so, hold the Ctrl key down while clicking on the procedures.

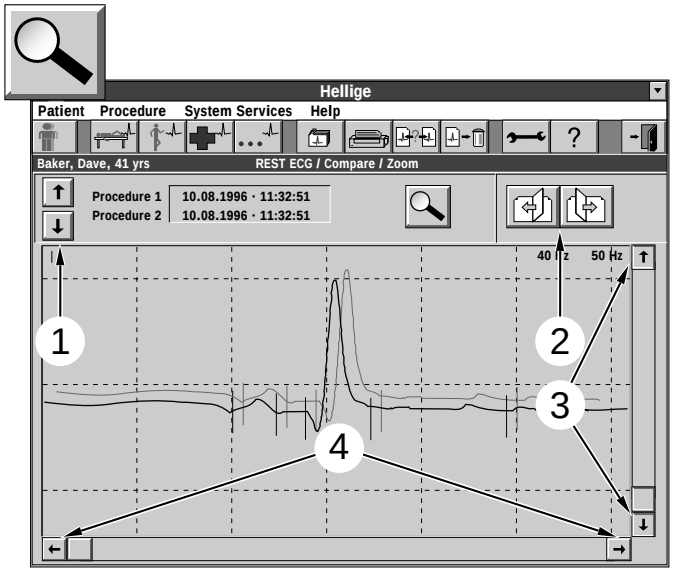


Figure 4.1-31. Comparing two zoomed ECG segments

1 *Displays the same QRS complexes in other leads*

2 *Displays the average beats, returns you to the 10-s ECG or to the interpretation*

3 *Moves ECG 2 up and down*

4 *Moves ECG 2 to the right and left*

For each ECG the screen shows 3 leads at a time (25 mm/s, 10 mm/mV). ECG 1 is displayed in the top half, ECG 2 below. Click buttons ↑ and ↓ to display the other ECG leads.

The 🔍 button allows you to select a portion of the ECG and display it at a larger scale. Identical segments of the two procedures are superimposed.

Click 🔍.

Move the cursor to the region of interest (the cursor becomes a magnifying glass) and click. You will see a display similar to that shown in Figure 4.1-31.

You can move ECG 2 up/down/right/left, using buttons ↑ ↓ and ← → .

You can perform measurements on the ECG (amplitudes, intervals, slopes) as described in section 4.1.4 “Measuring the ECG”.

Clicking 🔍 returns you to the 10-second ECG segments.

The median complexes and the interpretation can be compared in the same way. Click ⇨ and ⇦ to display them.

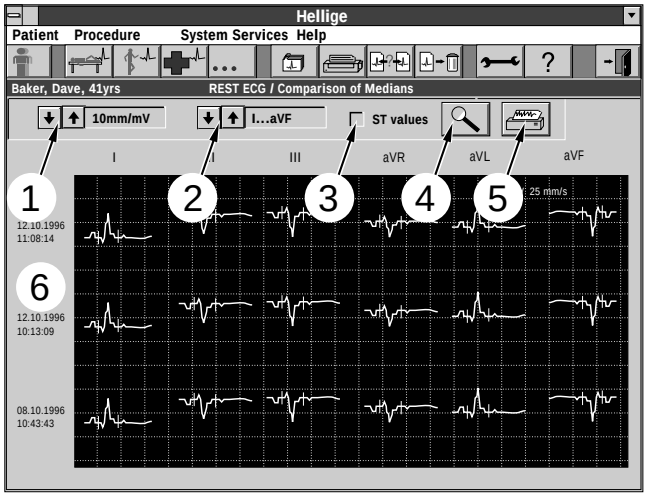


Figure 4.1-32. Comparing median complexes

1 *Changes the signal size*
2 *Displays the other 6 leads*
3 *Displays/removes the ST values*
4 *Activates the zoom function*
5 *Prints the screen*
6 *Procedure date*

Comparing Median Complexes from Multiple Resting ECGs

Click .

A window opens showing all resting ECGs of the patient in question (Figure 4.1-29).

Select 2 to 5 ECGs and click on OK to clear the window.

The next screen shows the median complexes of the selected procedures (Figure 4.1-32).

The signal size (amplitude) can be changed with ↑ ↓ (1, Figure 4.1-32). Other leads can be selected with ↑ ↓ (2).

If you wish to have the ST values annotated, check ☐ ST values.

Another useful function is the presentation of a large-scale single median complex together with the same ST beat of the other leads in the form of a so-called 3D graph:

First, click on , then on the ST beat you wish to see.

A display similar to Figure 4.1-33 will appear.

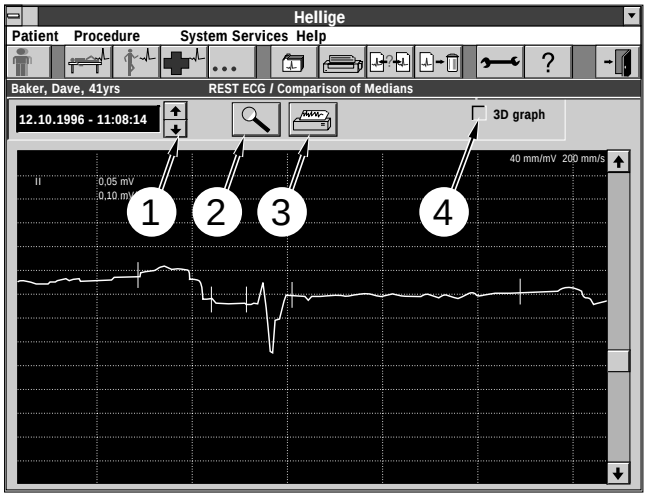


Figure 4.1-33. Zoomed display

1 For display of the median complex as shown from the other leads

2 To return to the ST comparison screen

3 To print out the screen display

4 To activate the 3D presentation

On this screen you can check ☐ 3D graph (4, Figure 4.1-33) to view a three-dimensional presentation of the beat (Figure 4.1-34).

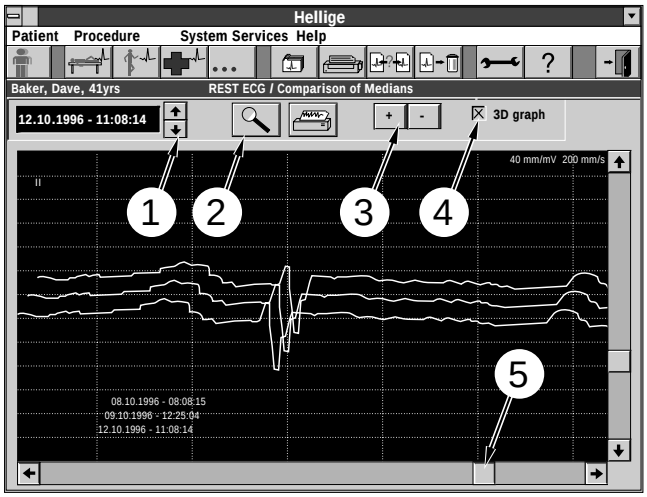


Figure 4.1-34. 3D presentation

1 For display of the same beat as shown from the other leads

2 To return to the ST comparison screen

3 To increase or reduce the distance between the waveforms

4 To return to the zoomed display

5 To select another viewing angle

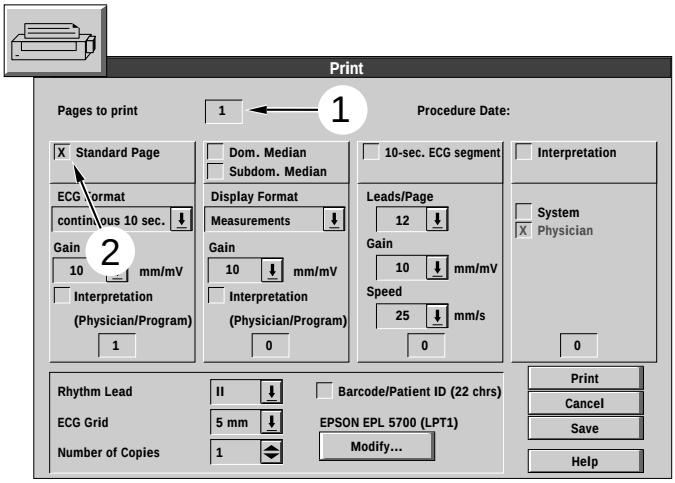


Figure 4.1-35. Resting ECG print setup screen

1 Number of pages of the entire report

2 Document selected for printout

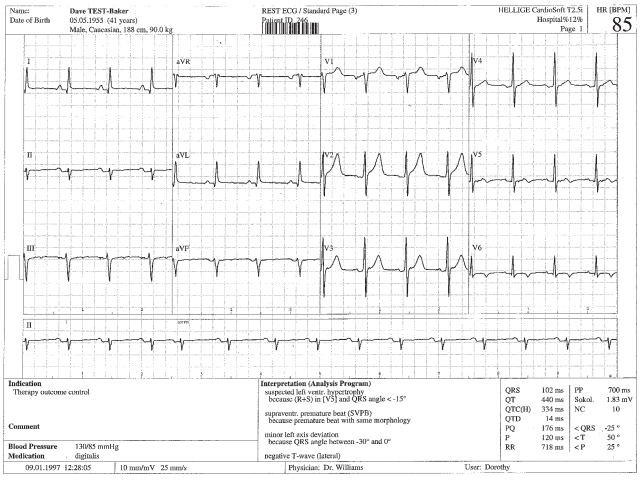


Figure 4.1-36. Report page, standard format

4.1.6 Printing the Resting ECG

The scope of the printed report is determined on the print setup screen (Figure 4.1-35).

Click to call up the print setup screen.

The report includes the following documents:

- Standard Page
- Medians
- 10-second ECG segments
- Interpretation

Clicking the box in front of each of these documents includes them in or excludes them from the report (check mark = included). The length of each document and of the overall report is also indicated.

The Print button initiates the printout.
The Save button saves the current settings.

Standard Page (Figure 4.1-36)

For the ECG display you can choose between:

continuous 10 sec:	first 5-second segment of the first set of six leads, second 5-second segment of the second set of six leads or
sync 5 sec/ sync 2.5 sec:	synchronized segments of all 12 leads (the first 5 seconds or the first 2.5 seconds)

medians: the dominant average beats (medians) will be printed

continuous 2.5 sec: 3 leads each of second 1 to 2.5, 2.5 to 5, 5 to 7.5, 7.5 to 10

2 x 6 ch. 50 mm/s: 2 pages, the first set of 6 leads from second 1 to 5, the second set of 6 leads from second 5 to 10

w/o. Arrhy 25 mm/s: without rhythm strip

w/o. Arrhy 50 mm/s: without rhythm strip

portrait: the standard page is printed in the vertical (portrait) format.

H1: 12 median complexes + V1, II, V5, V2, V3, V4

H1: 12 median complexes + I, II, III, V1, V2, V5

Dom. Median/Subdom. Median (Figure 4.1-37)

You can print a page with the dominant average medians and with the subdominant medians, if these were found as well. For more information, you may add either the measurements or the ST profile.

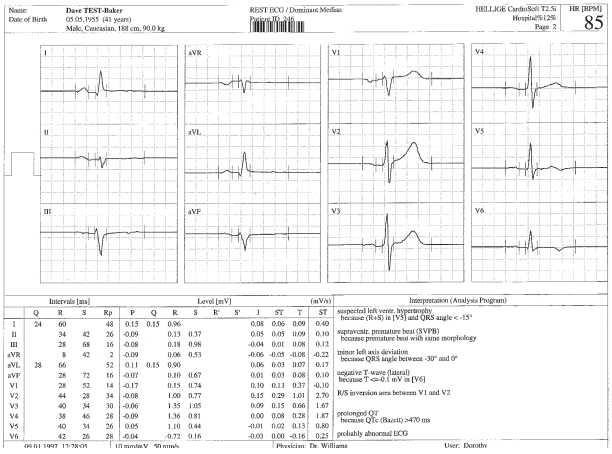


Figure 4.1-37. Report page, medians

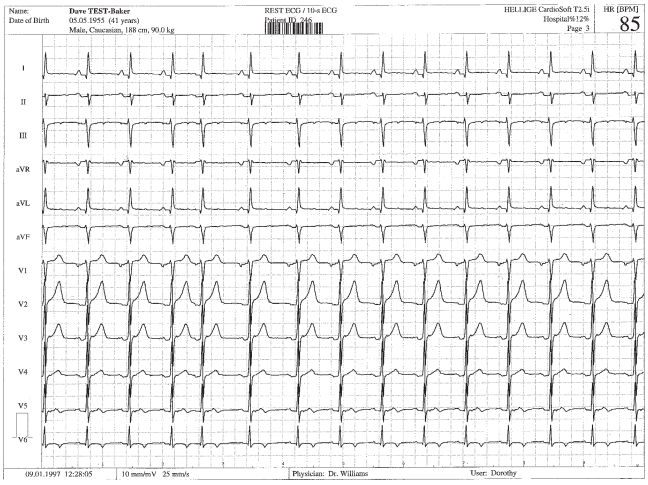


Figure 4.1-38. Report page, 10-s ECG segments

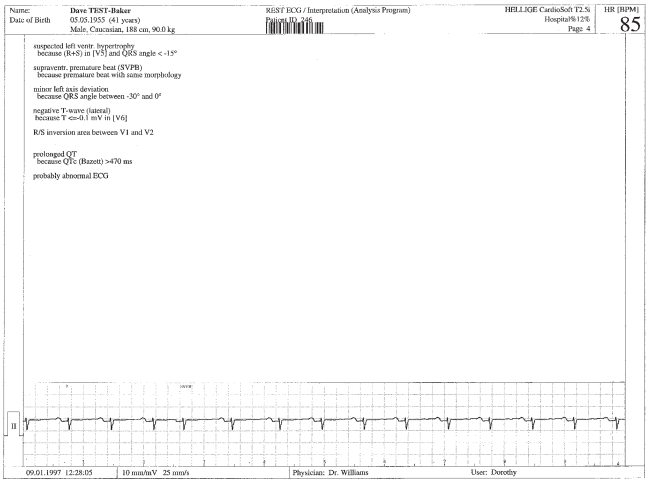


Figure 4.1-39. Report page, interpretation

10-second ECG segment (Figure 4.1-38)

Here you set up the system for printout of the full 10-second ECG. You can choose to print either 6 or 12 leads/page and you select the gain and paper speed. The resulting number of pages to be printed is indicated.

Interpretation (full) (Figure 4.1-39)

In this window you set up the system for printout of the full interpretation (interpretation as derived by the system and/or physician's interpretation).

Rhythm Lead

The standard page and the interpretation page include the 10-second ECG strip of the rhythm lead. However, you can select another channel to be printed.

Printer

Selection of the printer model and port (LPT) to which the printer is connected.

Barcode/Patient ID

The patient ID no. can be annotated on the report in the form of a barcode. This allows you to scan the code with a barcode reader and thus assign the report to the correct patient.

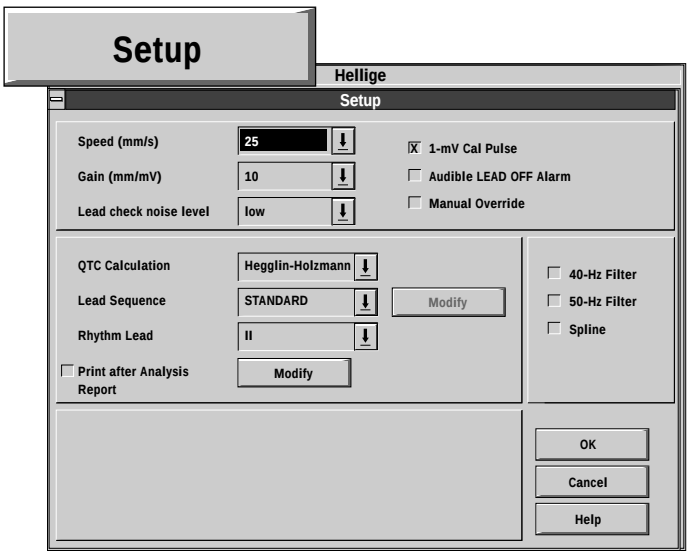


Figure 4.1-40. Setup menu

4.1.7 Setup

From the setup menu you can select a number of system settings to suit your personal needs and preferences. These settings will be retained. They are automatically activated each time the system is turned on.

Click **Setup** to display the setup menu screen (Figure 4.1-40).

Use this screen to select your personal system settings.

Adjustments are made in three different ways:

1 There is an arrow at the end of a box (↓).
Clicking this arrow will open a window which offers various options. Select the desired setting by clicking the mouse button.

2 There is a check box in front of the function. Click the box to enable or disable the function (☒ function enabled).

3 Click the **Modify...** button (for instance, to select the Lead sequence).

Speed
selects the trace sweep speed

Gain
selects the signal size (amplitude)

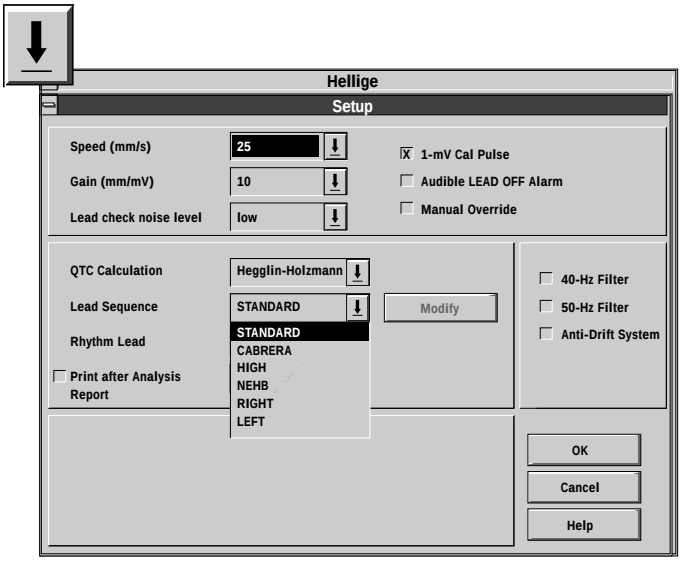


Figure 4.1-41. Lead sequence selection window

Lead check noise level

This is a measure of the quality of the acquired signal (signal-to-noise ratio). When there is too much signal noise at the electrode, the electrode is displayed yellow on the signal acquisition screen. The setting that you select here (low, middle, high) changes the threshold as of which the electrode is displayed yellow (high sensitivity to noise = low threshold).

1-mV Cal Pulse

display of 1-mV calibration pulse: yes or no (☒ yes)

Audible LEAD OFF Alarm

audible signal when an electrode is disconnected: yes or no (☒ yes)

Manual Override

When the function is enabled, the program will start the signal acquisition, even if not all electrodes are applied.

QTC Calculation

Equation for calculation of the QT interval: HEGGLIN-HOLZMANN or BAZETT.

Lead Sequence

In the lead sequence window you can assign the leads to the recording channels. Six lead sequences are predefined. Four of these (sequences 3 to 6) can be modified.

STANDARD:	I, II, III, aVR, aVL, aVF, V1...V6	*fixed*
CABRERA:	aVL, I, -aVR, II, aVF, III, V1...V6	
HIGH:	I, II, III, aVR, aVL, aVF, V1'...V6'	
NEHB:	I, II, III, aVR, aVL, aVF, D, A, J, I, II, III	
RIGHT:	I, II, III, aVR, aVL, aVF, V4R, V3R, V1, V2, V3, V4	
LEFT:	I, II, III, aVR, aVL, aVF, V4, V5, V6, V7, V8, V9	

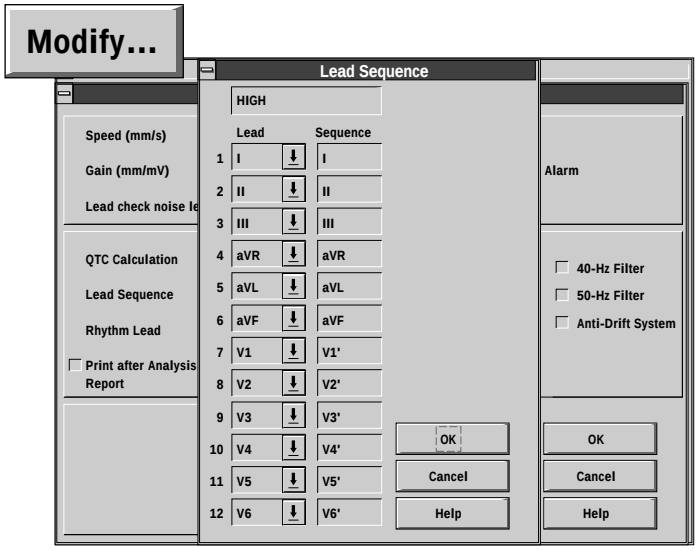


Figure 4.1-42. Modifying the lead sequence

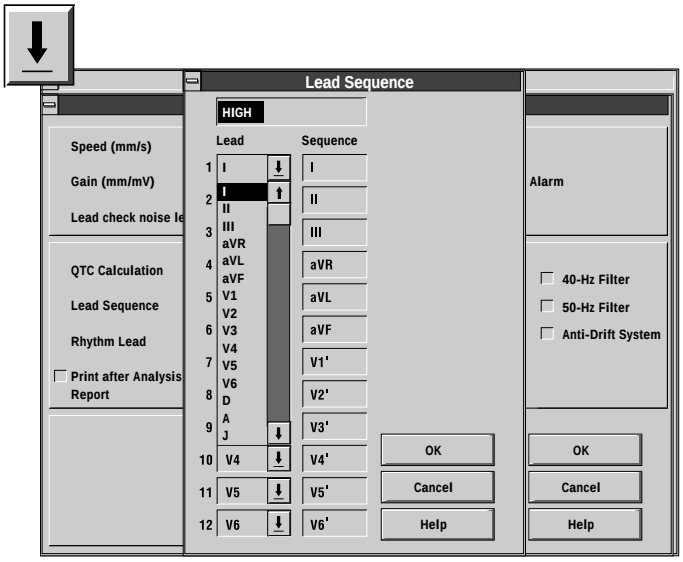


Figure 4.1-43. Modifying the lead sequence

Modifying the Lead Sequence

- Click ↓ to the right of Lead Sequence to open the lead sequence selection window (Figure 4.1-41).
- Click the sequence that you wish to modify (lead sequences 3 to 6 only).
- Click Modify... to open a window showing all channels (Figure 4.1-42). There is a window for each of the channels indicating the lead currently assigned to that channel. To select another lead click ↓ to display all available leads (Figure 4.1-43).
- Select the new lead to be recorded in the respective channel.
- Enter up to 4 characters in the “Designation” column to label the lead.

Once you have assigned a new lead to each of the channels, you can enter a name for the lead sequence in the headline.

- Move the cursor to the text box and click.
- Enter a name and select OK to clear the window.
- Click OK (modifications are saved) or Cancel (modifications are ignored) to clear the configuration screen.

Rhythm Lead
rhythm or reference lead

Print after Analysis
Do you wish to print the report set up on the screen mentioned above immediately after the ECG analysis or not.

Report Modify
Here you determine the scope of the report printed with the “Print after Analysis” command. The special configuration screen is described in detail in section 4.1.6 “Printing the Resting ECG”.

40-Hz Filter
enables or disables muscle filter (muscle filter on)

50-Hz/60-Hz Filter
enables or disables AC filter (AC filter on)

Spline
Enables or disables the Cubic Spline algorithm (automatic baseline correction, Spline on); the algorithm causes a signal delay of 4 seconds. On the signal acquisition and control screen the algorithm can be disabled temporarily to view the undelayed ECG signal.

4.1.8 Recording a Resting ECG (Brief Operating Instructions)

Turn on system and display the resting ECG screen

Enter new patient or retrieve patient from the database

Apply electrodes and check signal quality

Enter test information

Select procedure parameters (sweep speed, sensitivity, lead sequence)

Watch ECG traces and – when the most recent 10 seconds are without artifacts – start recording

Save procedure (when patient data were entered, the system saves the recording automatically)

The ECG traces are displayed

Scroll through the procedure report pages or call them up directly from the table of contents

Print the ECG

Proceed to next procedure or

Quit program

For your notes

4.2 The Exercise ECG

This section describes the operating steps necessary to conduct an exercise test. You will learn how to

- apply the electrodes and connect the patient
- enter the test demographics (indication, medication, comments, etc.)
- select a protocol and run the exercise test
- call up the report pages for on-screen review
- print reports
- specify system defaults that will be activated each time the system is turned on
- monitor remote test stations
- conduct an exercise test, using the function keypad

The brief operating instructions at the end of the section sum up what you have to do to record an exercise ECG.

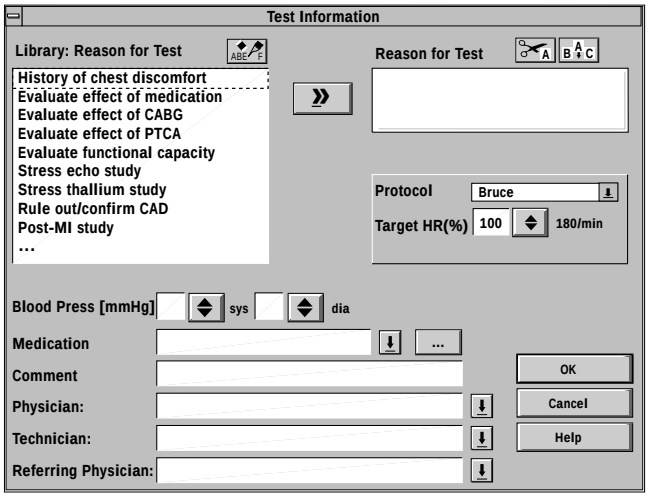


Figure 4.2-1. Dialog window for entry of the test information

4.2.1 Some Basic Facts

> ***Before recording your first exercise ECG, go to the defaults screen and choose the basic system settings (section 4.2.7 "Exercise Test Setup"). These settings will be retained and are automatically activated each time the system is turned on.***

Click on to start the program

After you have selected the patient, the system displays the dialog window for entry of the test information (Figure 4.2-1) (unless this option was deselected in the System configuration). We recommend applying the electrodes to the patient, following the instructions given in section 4.2.2, before entering the test demographics.

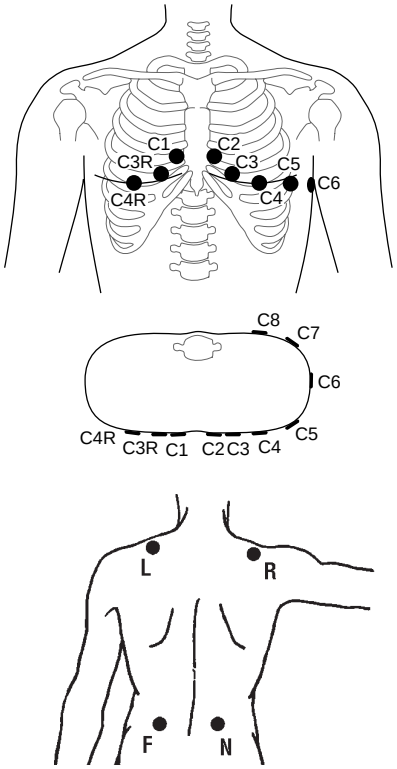


Figure 4.2-2. Electrode application points

- *C1* *in the 4th intercostal space at the right sternal edge*
- *C2* *in the 4th intercostal space at the left sternal edge*
- *C3* *at the level of the 5th rib midway between C2 and C4*
- *C4* *in the 5th intercostal space on the left midclavicular line*
- *C5* *on the left anterior axillary line between C4 and C6*
- *C6* *on the mid-axillary line at the level of C4*
- *C7* *in the 5th intercostal space on the left posterior axillary line*
- *C8* *in the 5th intercostal space on the left scapulary line*
- *R, L* *on the right and left shoulders*
- *N, F* *above the right and left kidneys*

4.2.2 Applying the Electrodes

Careful application of the electrodes is a prerequisite for obtaining an interference-free ECG. The signal acquisition screen immediately gives you a visual indication of your electrode technique and of the signal quality, provided the red R electrode is applied.

For quick, reliable and trouble-free application of the electrodes we recommend our Electrode Application System (refer to the Electrode Application System operator's manual).

As an alternative you can use our disposable electrodes (919 200 31, pkg. of 200).

Skin Preparation

* Shave the electrode application points, if necessary.
* Carefully degrease the application points with a cotton swab soaked in benzine.
* Prep the application points with skin prepping paste (EPICONT). To do so, apply a small amount of paste to the tip of a cotton swab. Place the tip against the skin at the electrode site and twirl the swab 4 to 5 times between your thumb and index finger, lightly pressing on the swab.
* Connect the electrode leads to the electrodes.
* Remove the backing paper from the electrodes and press the electrodes firmly into place.
* Secure each electrode lead with surgical tape.

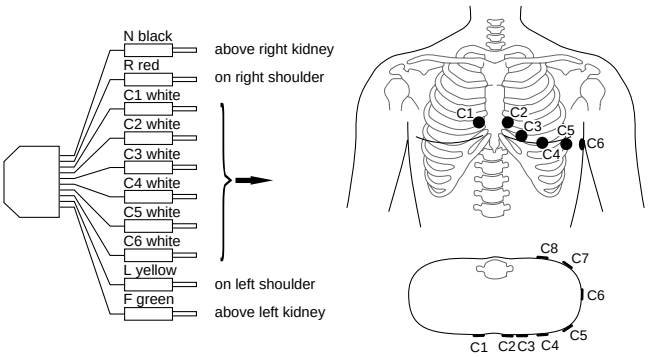


Figure 4.2-3. Connecting the patient cable (10-wire, standard ECG leads)

> ☞ ***Please observe the information given in sections 7.1 "Artifact Due to Poor Electrode Application", 7.2 "ECGs of Pacemaker Patients" and 7.3 "ECG Recording During Defibrillation" in the appendix.***

> ☞ ***The red R electrode is the reference electrode. Placement and signal quality of all other electrodes can be assessed on the signal acquisition screen only when this electrode is applied.***

* Secure the patient cable with a holder 303 441 61 (bicycle ergometer) or with a strap 923 096 72 (treadmill).

Electrode Application Points for Standard Leads

(I, II, III, aVR, aVL, aVF, V1 to V6)

Four limb and six chest electrodes are usually required for the acquisition of the standard leads. In stress testing, however, we recommend attaching the limb electrodes on the shoulders (where there are no muscles) or above the kidneys (Figure 4.2-2).

* Connect the patient cable as shown in Figure 4.2-3.

* Secure the electrode distributor of the patient cable (chest strap or holder).

* Connect the patient cable to the device (type CF signal input: highly isolated, suitable for intracardiac application, defibrillation-proof).

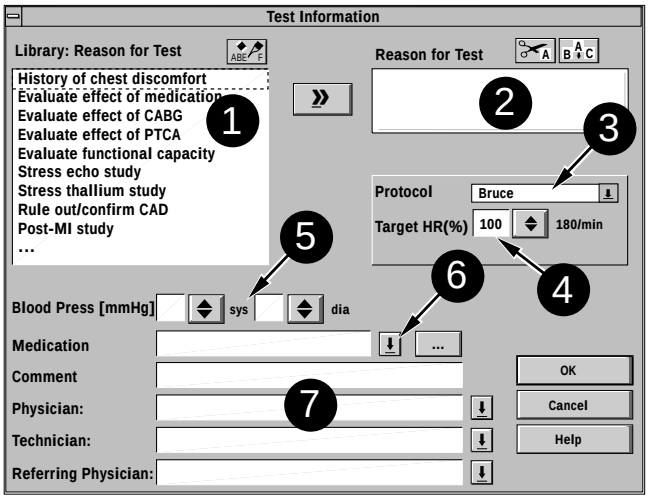


Figure 4.2-4. Test Information dialog window

1 The standard reasons for test

2 The patient's reason for test

3 Test protocol

4 Target HR in %

5 Blood-pressure readings

6 Medication

7 Dialog boxes for comments, the physician's name and the technician's (user's) name

4.2.3 Entering the Test Information

The test information window allows you to make all entries and settings relevant to the test.

These are:

– the reason(s) for the test

– the test protocol

– the target heart rate

– the blood-pressure readings

– the medication(s)

– comments

– the names of the physician, of the referring physician and/or user (ECG technician).

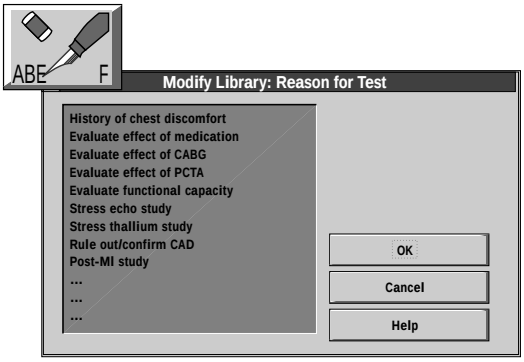


Figure 4.2-5. Window for entry of standard reasons for test

> ***A reason for test is easily copied from the library to the right window by double-clicking!***

Copying Reasons for Test to the Patient Indication Window

- Highlight the statement by clicking.
- Click the [>>] button.
- If you wish to delete a copied statement or part of it, highlight the words in question and click [A].
- The deleted words can be inserted in another position by placing the cursor there and clicking [A B C].
- You can also enter a reason for test directly by moving the cursor to the desired position and typing the text.

Editing the Library

- Click [ABF].

This will open the library window (Figure 4.2-5).

- Move the cursor to the desired position in the list and click the mouse button.
- Enter a reason for test, and press [↵] on the keyboard. The cursor moves to the beginning of the next line.
- In this manner you may enter up to 12 standard reasons. When the window is full, it will not accept any more entries. Click [OK] to clear the window.

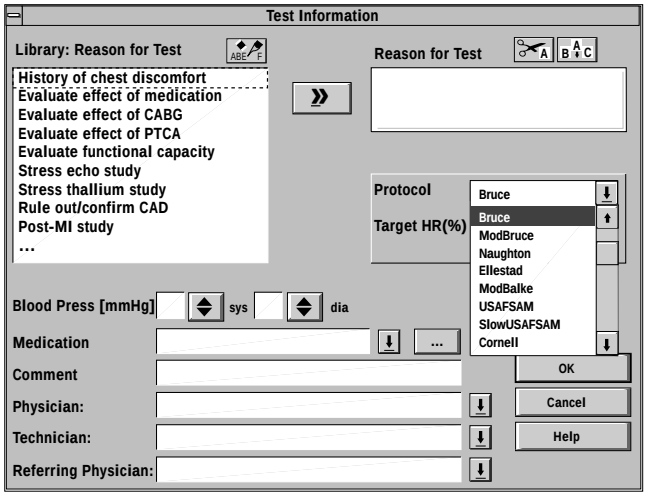


Figure 4.2-6. Protocol selection window

Selecting a Test Protocol

The program defaults to the test protocol specified in the Exercise Test Setup (section 4.2.7). On this screen, however, you can choose another protocol for the present test.

Click on ↓.

The protocol list box opens (Figure 4.2-6).

Click on the protocol you wish to use.

Adjusting the Target HR

The target heart rate that the patient is expected to attain during the test can either be adjusted manually, or the system will calculate this value automatically (section 4.2.7 “Exercise-Test Setup ”). Furthermore, you can change the calculated or entered value (e.g. 90% of 180 = 162). This setting will be retained.

Entering Blood-Pressure Readings

Blood-pressure readings are either entered directly via the keyboard or they are selected and changed in steps of 5 mmHg by clicking on the arrow boxes. In the systolic box, the values start from 120 mmHg, in the diastolic box, from 80 mmHg.

Click on ▲ to display and increase the value, or click on ▼ to decrease the value.

Move the cursor to the “sys” box and click the left mouse button.

Enter the value via the keyboard.

Proceed in the same manner to enter the diastolic value.

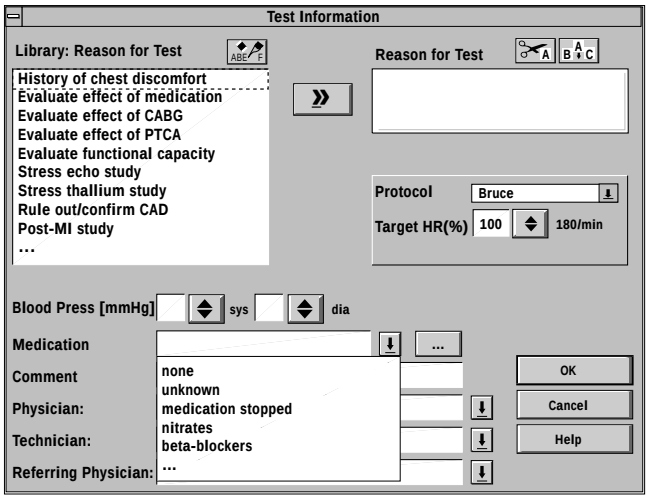


Figure 4.2-7. List of medication groups

> ***The physician is responsible for assigning drugs to a medication group.***

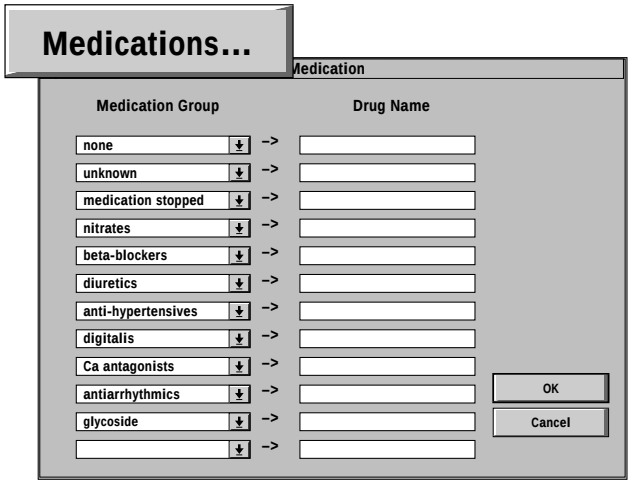


Figure 4.2-8. Assigning a drug to a medication group

Selecting a Medication, Assigning a Drug Name to a Medication Group

You can select a medication from a list of medications ⬇. You can also select 4 more medications and assign specific drugs to the medication groups to include these in the list instead of the group name. The window permits entry of the medication dose ...

Making a Selection

- Click on ⬇ to open the medication list box (Figure 4.2-7).
- Select one of the medications.
- To select additional medications, to enter a medication dose or to assign drug names to medication groups, click ...

Assigning Drugs to a Medication Group

- Click on Medications...

A window opens, showing several medication group names (Figure 4.2-8). There is a drug name window for each of these groups. Click on the respective text box, if you wish to enter a name. Then type the drug name.

Furthermore, you are free to arrange the medication groups any way you want. To do so

- Click on the ⬇ at the end of the group name box.

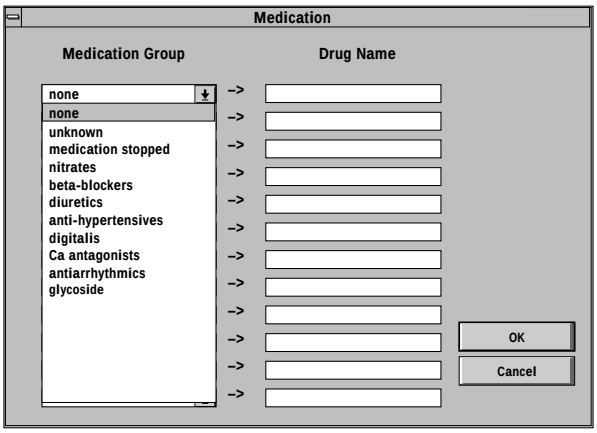


Figure 4.2-9. Editing the medication group

This brings up a new window where you can choose one of the group names (Figure 4.2-9).

Click on the drug name box and enter the name

Click on OK to clear the window.

Entering Comments

If you wish to enter a comment on the test procedure, click in the “Comment” text box and key in the text.

Physician’s/User’s Name

The names of the physician and user can either be entered here (click in the text box and type the name), or they can be selected from the list of the registered system users (section 6.1 “System Configuration”).

Click on ↓ and choose a name from the list by clicking on it.

Exiting the Test Information Screen

Once you have entered all test information, you can either

– clear the window with OK and start conducting the exercise test or

– clear the window with Cancel (in this case the test demographics will be ignored and are not assigned to the test) to display the preacquisition screen

From the preacquisition screen, you can

– check the signal quality

– return to the test information screen

– access the system setup screen

– temporarily modify the selected phase with Modify... (enter test information before modifying the test phase, otherwise the changes will be lost).

Please refer to section 4.2.7 for a detailed explanation of the preacquisition screen and the exercise-test setup.

If you select OK to clear the window, the entries just made will be assigned to the present test procedure and the preacquisition screen will appear. In the next section we will explain how an exercise test is conducted.

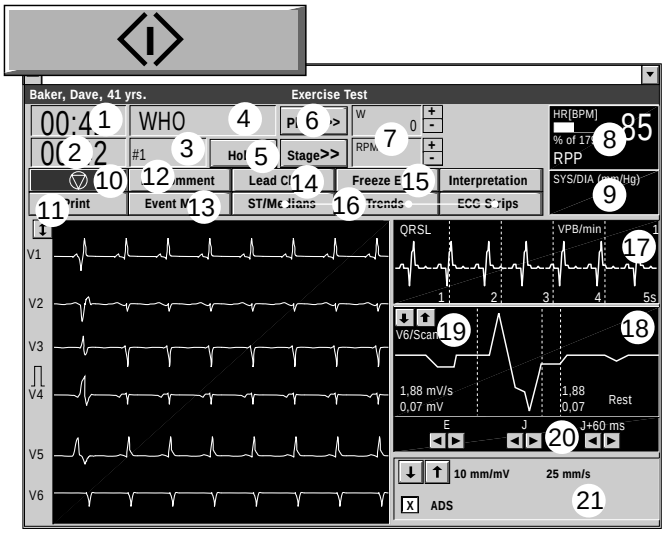


Figure 4.2-10. Signal acquisition screen for a bicycle exercise test

1 *Time elapsed in current phase*
2 *Time elapsed in stage*
3 *Stage number*
4 *Current phase and button to modify the protocol*
5 *Buttons to hold the stage and to proceed to the next stage*
6 *Button to proceed to the next phase*
7 *Current load and revolutions/minute, buttons to increase or decrease the load in steps of 5 Watts*
8 *Windows indicating the heart rate and the rate-pressure product (RPP) (HR in red when max. HR is exceeded), diagram of the % of the max. HR*
9 *Blood-pressure values (with some ergometers the cuff pressure is indicated here during a BP measurement)*
10 *Button to abort the test*
11 *Button to initiate a printout (laser printer or thermal-array printer)*
12 *Button for entry of comments and blood pressure*
13 *Button to mark an event episode (the episode is saved at the same time)*
14 *Button to verify the ECG signal quality (all leads)*
15 *Button to freeze and release the signal traces*
16 *Buttons to display the ST profiles and medians, the trends and the stored ECG*
17 *Results of the arrhythmia analysis (complex ectopy in red) and number of VPB/min*
18 *ST median beat window and ST analysis results (resting beat analysis results are shown with a different color)*
19 *Button for selection of another lead*
20 *Buttons for adjustment of the E, J, and J+X point (only when "Manual" has been selected in the Defaults menu)*
21 *Procedure parameters and buttons to modify the signal sensitivity and to temporarily disable the ADS (anti-drift system)*

4.2.4 Running an Exercise Test

The signal acquisition screen appears when you have entered the test information and clear the dialog window with OK. For bicycle ergometers the screen is similar to Figure 4.2-10, for treadmills it is similar to Figure 4.2-11. Please take a few seconds to become familiar with all the details shown on this screen, before proceeding to start the test.

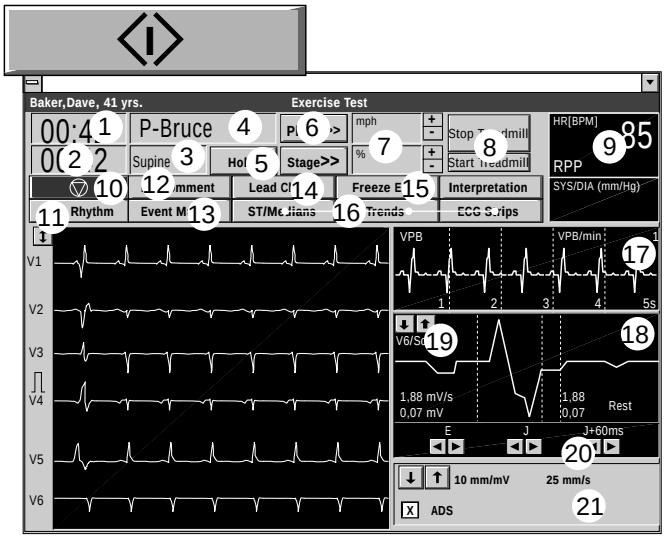


Figure 4.2-11. Signal acquisition screen for a treadmill exercise test

1 *Time elapsed in current phase*
2 *Time elapsed in current stage*
3 *Stage number/name*
4 *Current phase and button to modify protocol*
5 *Buttons to hold the stage and to proceed to the next stage*
6 *Button to proceed to the next phase*
7 *Current speed and grade, buttons to increase or decrease the speed and the grade*
8 *Buttons to start and stop the treadmill (protocol continues)*
9 *Windows indicating the heart rate, rate-pressure product (RPP) and the blood pressure*
10 *Button to abort the test*
11 *Button to initiate a printout (laser printer or thermal-array printer)*
12 *Button for entry of comments and blood pressure*
13 *Button to mark an event episode (the episode is saved at the same time)*
14 *Button to verify the ECG signal quality (all leads)*
15 *Button to freeze and release the signal traces*

The Signal Acquisition Screen of an Exercise Test

The signal acquisition screen (Figure 4-11) of the exercise test presents the following information:

– the current load and RPM or speed and grade (7)

– the current stage (3) and the time elapsed in that stage (2)

– the current phase (4) and the time elapsed in that phase (1)

– the heart rate, RPP and blood pressure (9)

– the results of the arrhythmia analysis (complex ectopy in red) and number of VPB/min (17)

– the ST analysis results compared with the resting beat analysis results (18) (“Scan” indicates that the lead with the most prominent ST depression is displayed (leads I, aVR, aVL, V1 and V2 are not considered))

– various procedure parameters (21)

16 *Buttons to display the ST profiles and medians, the trends and the stored 12-lead ECG*
17 *Results of the arrhythmia analysis (complex ectopy in red) and number of VPB/min*
18 *ST median beat window and ST analysis results (resting beat analysis results are shown with a different color)*
19 *Button for selection of another lead*
20 *Buttons for adjustment of the E, J, and J+X point (only when “Manual” has been selected in the Defaults menu)*
21 *Procedure parameters and buttons to modify the signal sensitivity and to temporarily disable the ADS (anti-drift system)*

The Elements of an Exercise Test

Ergometers without Digital Communication Interface (e.g., MEDITRONIC M 400)

With these ergometers, the test follows the stored test phases. This is to say that the initial load and load increase displayed in the protocol have to be adjusted manually at the ergometer. Manual modifications of the protocol (load increase or selection of the next test phase) must also be repeated at the ergometer.

- On the setup screen (section 4.2.7) select the “internal” ergometer.
- If you wish to obtain a recording at the end of each load stage only, set the “ECG Rec. Inter. EI” to the duration of the load stage.
- Select a protocol and adjust the required initial load at the ergometer.
- Click the ◁▷ button. Wait for the first ST measurement to be displayed which is to be saved as the reference beat at rest (option) (18, Figure 4.2-10 and Figure 4.2-11).

As trend values are saved at 30-second intervals, we recommend that you wait approx. 30 seconds before starting to pedal.

- Then press the Phase >> button and ask the test subject to start pedalling.

Window (2) in Figure 4.2-10/4.2-11 indicates the remaining time in the current stage, while window (1) shows the time elapsed in that phase.

At the end of the load stage, the load increase displayed by the program must be adjusted at the ergometer. As a general rule you are required to repeat all load changes at the ergometer as demanded by the program.

During the test you can

- advance to the next load stage with Stage >>
- continue at the same load with Hold
- modify the load in steps of 5 Watts with + 5 and - 5
- advance to the recovery phase with Phase >> (upon completion of the last stage, the program automatically activates the recovery phase)
- terminate the test with ▽.

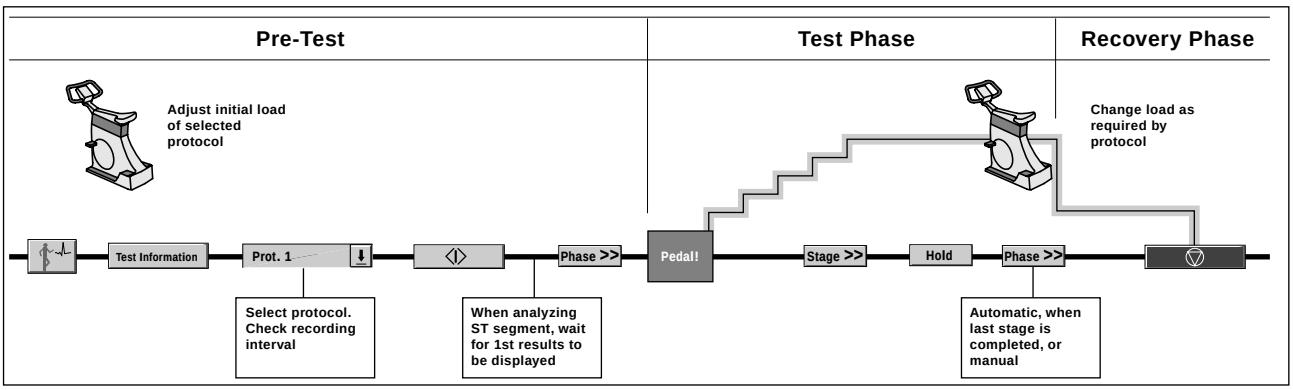


Figure 4.2-12. Program sequence with MEDITRONIC M 400

Ergometers without Digital Communication Interface but with Remote Start Capability (e.g., MEDITRONIC M 40)

As above, but there is no need to select the next phase manually at the ergometer, as this is done by the remote start signal.

- On the setup screen (section 4.2.7) select the “intern. remote start” ergometer.
- If you wish to obtain a recording at the end of each load stage only, set the “ECG Rec. Inter. EI” to 00:00 min.
- For “Time in stage” (TS) enter a time which is considerably longer than the corresponding value at the ergometer.
- Select a protocol and adjust the corresponding initial load at the ergometer.
- Click the ◇ button. Wait for the first ST measurement to be displayed (option) (18, Figure 4.2-10/ 4.2-11).

As trend values are saved at 30-second intervals, we recommend that you wait approx. 30 seconds before starting to pedal.

- Then press the Phase >> button and ask the test subject to start pedalling. If your ergometer sends a remote start impulse when the patient starts pedalling, there is no need to click the Phase >> button.

Window (2) in Figure 4.2-10 indicates the remaining time in the current stage, while window (1) shows the time elapsed in that phase.

During the test you can

- modify the load in steps of 5 Watts with + 5 and - 5; do not forget to make the same adjustments at the ergometer
- advance to the recovery phase with Phase >> (upon completion of the last stage, the program automatically activates the recovery phase)
- terminate the test with ▽.

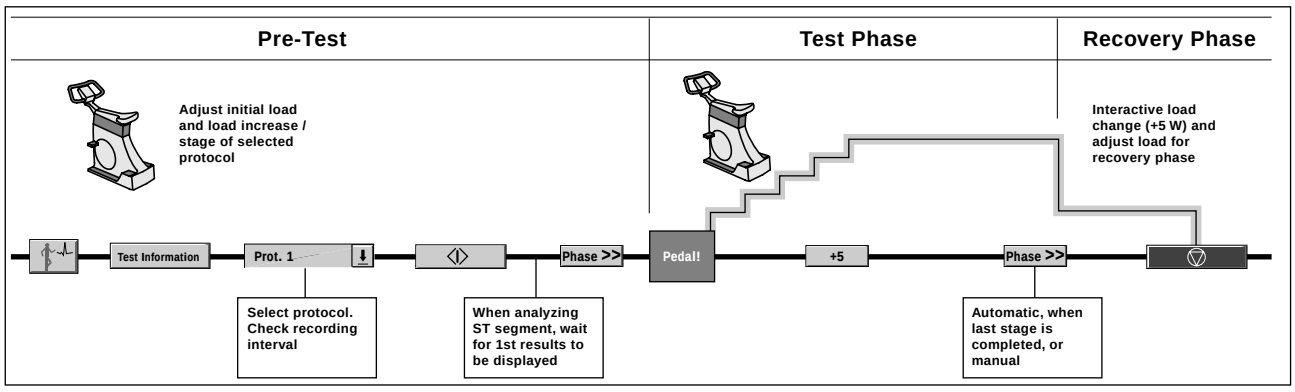

Pre-Test
Test Phase
Recovery Phase
Adjust initial load and load increase / stage of selected protocol
Interactive load change (+5 W) and adjust load for recovery phase
Test Information
Prot. 1
Phase >>
Pedal!
+5
Phase >>
Select protocol. Check recording interval
When analyzing ST segment, wait for 1st results to be displayed
Automatic, when last stage is completed, or manual

Figure 4.2-13. Program sequence with MEDITRONIC M 40

Ergometers with Digital Communication Interface (ERGOCOMP EC 560/ECB 561 / ERGOLINE 900/900L, EC 1200 V3.52)

The EC 1200 will display the version number when turned on. The following explanations refer to version 3.52 or higher (upgrade, if possible). For older versions, see section “M 700 and EC 1200”.

With these ergometers the selected protocol fully controls the test procedure. The ergometer operating controls are inoperative. Only blood pressure measurements can be taken manually. Refer to Appendix 6 “Connecting External Devices”.

EC 1200
Blood pressure intervals are valid only for external BP meters (appendix, section 6). BP meters must be connected directly when used with EC 1200 version 3.52 and higher. They are controlled by the stage time. The BP intervals are ignored.

On the setup screen (section 4.2.7) select
“ERGA” for EC 560/ECB 561,
“ERG 900” for ERGOLINE 900/900L and
“EC 1200 (V3.52)” for EC 1200 version 3.52 or higher.

With ERG 900, select the recovery phase “recovery ERG 900” (25 W, 1 minute, then 0 W) only if you expect to do a low-impact test. The BP meter will then respond more promptly to the load decrease.

Select a protocol.

Click the ◇▷ button.

A blood pressure measurement is now taken automatically, if configured. Wait until the readings are available or until the first ST measurement is displayed (option) (18, Figure 4.2-10).

As trend values are saved at 30-second intervals, we recommend that you wait approx. 30 seconds before starting to pedal.

* Ask the test subject to start pedalling.

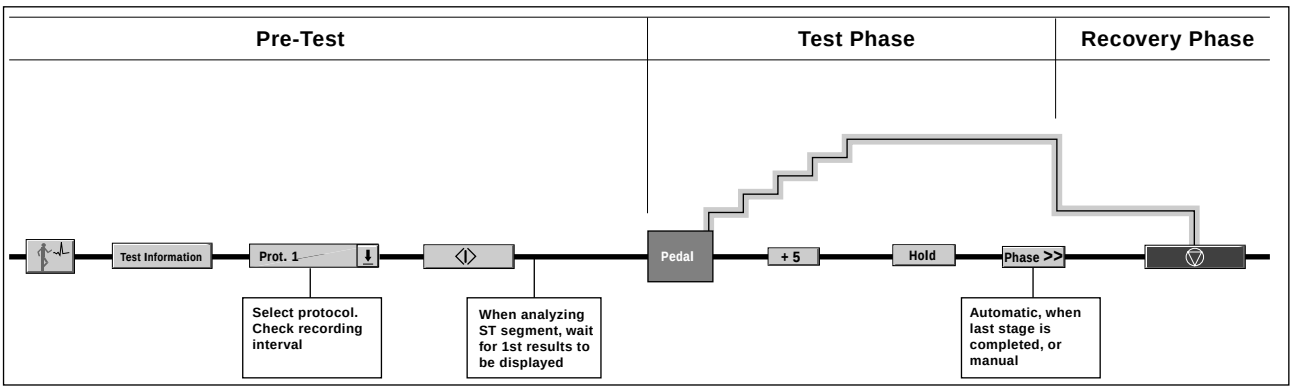


Figure 4.2-14. Program sequence with ERGOCOMP EC 560 / ECB 561

Window (2) in Figure 4.2-10 indicates the remaining time in the current stage, while window (1) shows the time elapsed in that phase.

During the test you can

- hold the stage with Hold (must be pressed 5 s before the end of a stage at the latest).
- advance to the next load stage with Stage >> (ERGOLINE 900/900L only)
- modify the load in steps of 5 Watts with + 5 and - 5 (with EC 1200 V3.52: next stage, previous stage, but never below initial load)
- advance to the recovery phase with Phase >> (upon completion of the last stage, the program automatically activates the recovery phase)
- terminate the test with ▽.

When the number of revolutions is low, the EC 1200 will automatically activate a load of 15 Watts and increase the load to the old value when the speed picks up again. During that time, the buttons Stage >>, + and - are inactive and the program will not proceed to the next load stage.

M 700 and EC 1200

M 700

In conjunction with M 700 ergometers too, the selected protocol fully controls the test procedure. During a test, load changes are only possible at the ergometer and only for the user-programmed phases. If you wish to create custom protocols you will have to use the phases stored in the ergometer.

On the setup screen (section 4.2.7) select the “ERGS” ergometer.

If you wish to obtain a recording at the end of each load stage only, set the “ECG Rec. Inter. EI” to 00:00 min.

Select a protocol.

Click the button.

A blood pressure measurement is now taken automatically, if configured. Wait until the readings are available or until the first ST measurement is displayed (option) (18, Figure 4.2-10).

* Ask the test subject to start pedalling.

Window (2) in Figure 4.2-10 indicates the remaining time in the current stage, while window (1) shows the time elapsed in that phase.

During the test you can

* modify the load at the ergometer, but only for your own custom-programmed phases
* advance to the recovery phase with

* terminate the test with .

EC 1200

This ergometer comes with 7 preprogrammed phases (6 exercise phases, 1 recovery phase). In addition there are five free phases.

In the program, 10 protocols have been created from these phases. You are free to modify these protocols as needed.

Phase No.	Name on Ergometer Display
8	OWN PROGRAM 1
9	OWN PROGRAM 2
10	OWN PROGRAM 3
11	OWN PROGRAM 4
12	OWN PROGRAM 5
1	WHO
2	ICSPE
3	ST. FRANCE
4	WHO NEW
5	HOLLMANN
6	REHA
7	not available for EC 1200
32	RECOVERY

If you call up an unconfigured phase (see above), the ergometer runs idle.

On the setup screen (section 4.2.7) select the “ERGS” ergometer.

If you wish to obtain a recording at the end of each load stage only, set the “ECG Rec. Inter. EI” to 00:00 min.

Select a protocol.

Click the ◁▷ button.

Wait until the first ST measurement is displayed (option) (18, Figure 4.2-10).

As trend values are saved at 30-second intervals, we recommend that you wait approx. 30 seconds before starting to pedal.

* Ask the test subject to start pedalling.

Window (2) in Figure 4.2-10 indicates the remaining time in the current stage, while window (1) shows the time elapsed in that phase.

During the test you can

modify the load at the ergometer

advance to the recovery phase with Phase >>

terminate the test with ▽.

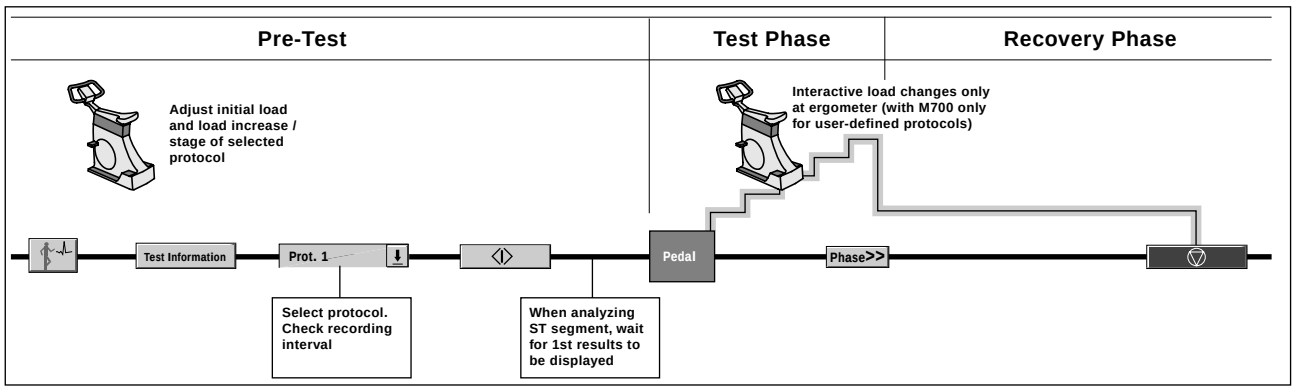

Pre-Test
Test Phase
Recovery Phase
Adjust initial load and load increase / stage of selected protocol
Interactive load changes only at ergometer (with M700 only for user-defined protocols)
Test Information
Prot. 1
Pedal
Phase>>
Select protocol. Check recording interval
When analyzing ST segment, wait for 1st results to be displayed

Figure 4.2-15. Program sequence with MEDITRONIC M 700 / ERGOCOMP EC 1200

☞ ***The treadmill can be stopped at any time with the emergency stop button.***

☞ ***When using the treadmill model TM400E, it is important to adjust the same unit of speed measurement at the ergometer and at the CardioSys system (km/h or mph).***

☞ ***If the speed is "0" in one of the stages, the treadmill switches off and can only be restarted with the*** [Start Treadmill] ***button.***

☞ ***If the treadmill is stopped with the*** [Stop Treadmill] ***button or with the emergency stop button, the speed and grade readout is "**.*". Wait until this readout disappears before restarting the treadmill with*** [Start Treadmill].

Treadmills

From the setup menu (section 4.2.7), item "Ergom./ Treadmill" select:
- "Internal Treadmill" for treadmills without digital interface
- "Series 2000" for treadmills 1800, 1900, T2000
- "TM 400E" for Trackmaster treadmills TM 310, TM 400E

Select a test protocol.

Click on [◁▷].

At the beginning the program invokes the first stage (supine) of the pre-test phase.

At this stage, the resting ECG of the supine patient is recorded. Continue collecting the ECG signal until you see the first ST analysis results (18, Figure 4.2-11) or the results of the first BP measurement.

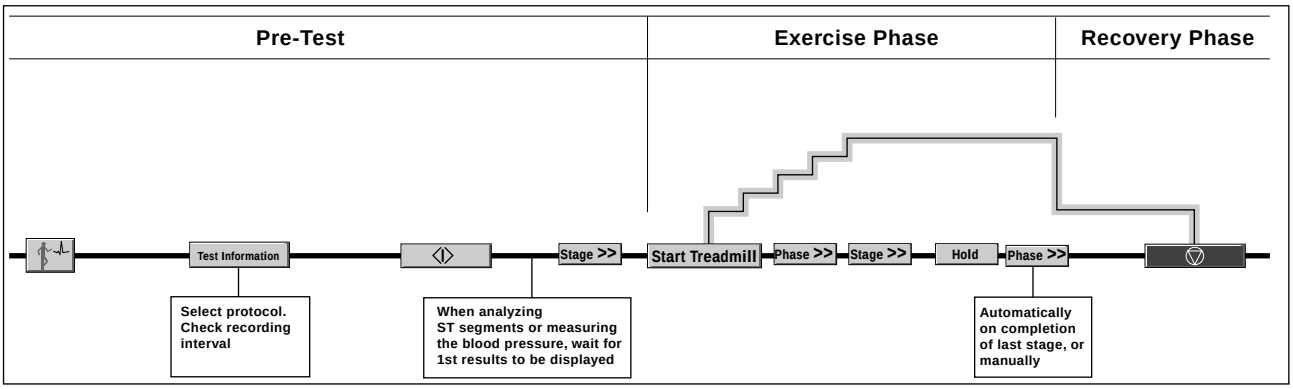


Figure 4.2-16. Program sequence for the treadmill test

☞ ***Pressing the [+] or [-] button cancels the automatic program sequence and activates the manual mode (phase name "Manual"). The program maintains the current stage for reasons of safety and the Hold and Stage >> buttons are locked. The test can only be controlled manually with the [+] and [-] keys (speed, grade). When you activate [+] and [-] again after a pause of approx. 15 seconds, the program displays the next higher stage number. With the Phase >> button you advance to the next test phase.***

☞ ***If the treadmill is stopped with the Stop Treadmill button or with the emergency stop button, the speed and grade readout is "**.*". Wait until this readout disappears before restarting the treadmill with Start Treadmill.***

Then you can proceed to the next stage (Stage >> button, 5, Figure 4.2-11) to record the ECG of the patient standing upright.

The next stage is reserved for recording the ECG of the hyperventilating patient.

Then the warm-up stage follows, in which the patient gets used to the treadmill exercise.

Proceed to the next stage and start the treadmill with the Start Treadmill button (8, Figure 4.2-11).

Once the patient is familiar with walking on the treadmill, initiate the actual test by clicking on Phase >> or by pressing the "start exercise" button on the function keypad.

From now on, the program controls the entire test including the recovery phase.

You can abort the test at any time by clicking the ▽ button.

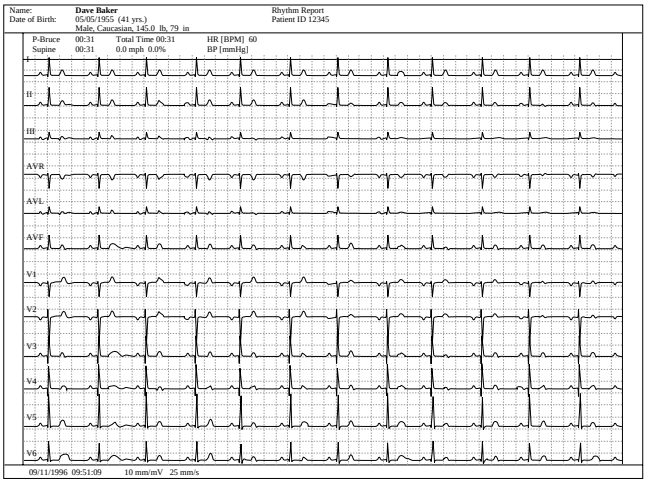


Figure 4.2-17. Example of a 12-lead rhythm report initiated with Print Rhythm *(thermal printer)*

During the test you can:

(the reference numbers refer to Figures 4.2-10 and 4.2-11)

– increase or decrease the speed and grade (7) (if you interrupt the automatic program, the Hold and Stage >> buttons are disabled and you have to control the rest of the test manually) or prevent an automatic increase or decrease with Hold (5)

– proceed to the next stage with Stage >> (5)

– proceed to the next phase with Phase >> (6)

– briefly stop the treadmill during the test and restart it with Stop Treadmill and Start Treadmill (8)

– abort the test with ▽ (10)

– initiate a printout with Print Rhythm (11) (the laser printer will print 1 page with approximately 4 seconds of ECG data and the median beats, the thermal array printer will print continuous rhythm (Figure 4.2-17) until stopped again with Stop Rhythm).

– verify the ECG signal quality (14)

– freeze the ECG (15) (the screen display only, one real-time lead continues to be displayed for monitoring)

– display an event marker (13) (an event episode is stored at the same time comprising a segment 5 seconds before and 5 seconds after the mark)

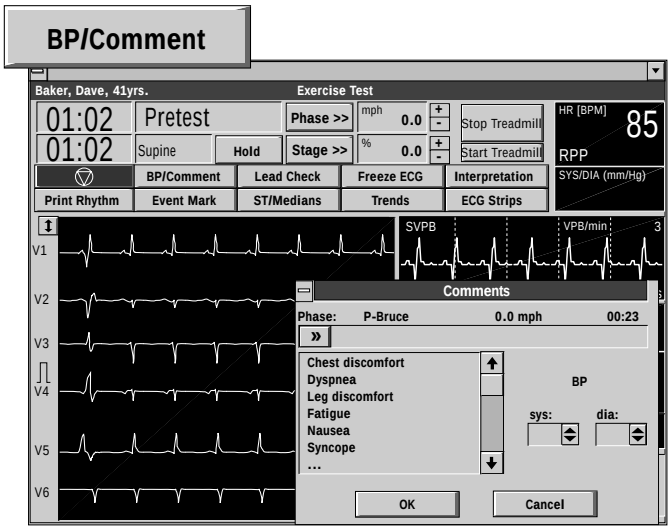


Figure 4.2-18. Dialog box for entry of comments and blood pressure

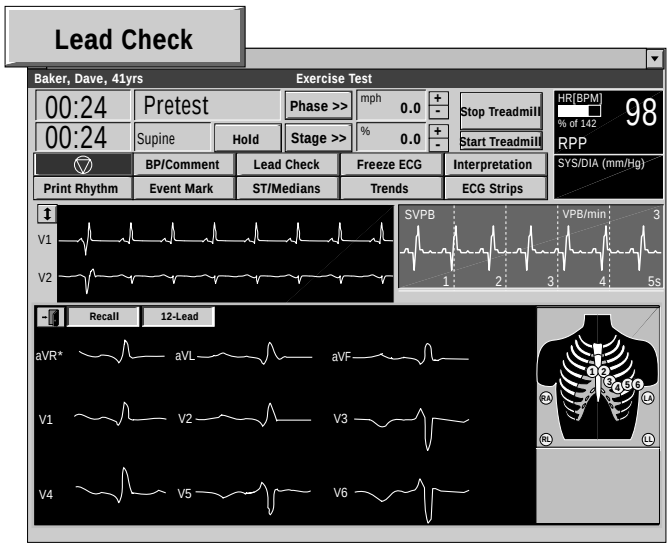


Figure 4.2-19. Lead check screen

– display ST measurement results of the other acquired leads (19), “Scan” indicates that the lead with the most significant ST depression is displayed automatically (leads I, aVR, aVL, V1 and V2 are ignored)

– adjust the reference points E, J and J+X (if the corresponding option was set to “Manual” in the setup menu)

– modify the sensitivity (21)

– enter comments and/or BP readings. To do so

Click on [BP/Comment] to open the dialog box (Figure 4.2-18).

Click on a comment, then click on [>>] to copy the comment to the text box (or double-click on a comment).

Enter the blood-pressure readings by clicking on the arrows (systolic value, TAB, diastolic value, ↵).

Click on [OK] to clear the dialog box.

click on [Lead Check] to display the lead segments for verification of the signal quality (Figure 4.2-19).

The [Recall] and [12-Lead] buttons are displayed only when the thermal-array printer is connected. These buttons are used to initiate an ECG printout. The print format is defined in the setup (section 4.2.7 “Exercise-Test Setup”, “In-Test Reports”).

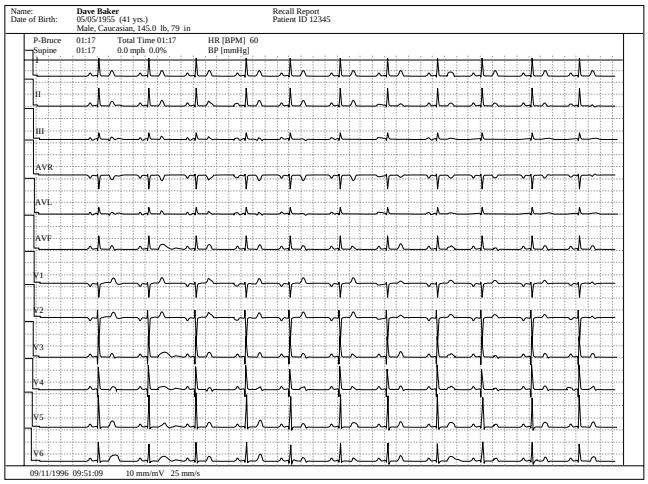


Figure 4.2-20. 12-lead recall report

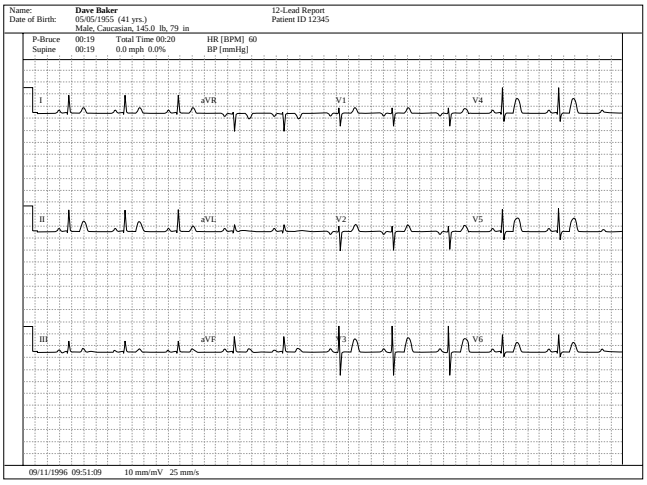


Figure 4.2.21. 12-lead report (4 x 2.5 s)

Recall prints the most recent 10 seconds of the ECG (3, 6, or 12 leads) (Figure 4.2-20).

12-Lead prints the 10-second ECG acquired after clicking on the button in the preconfigured format (4x2.5s, 2x5s, 1x5s) (Figures 4.2-21, 4.2-22, 4.2-23).

Click on to clear the lead check screen.

Recall and 12-Lead reports are printed only when option "print" or "print & save" is selected for "Manual Recording" in the Setup menu.

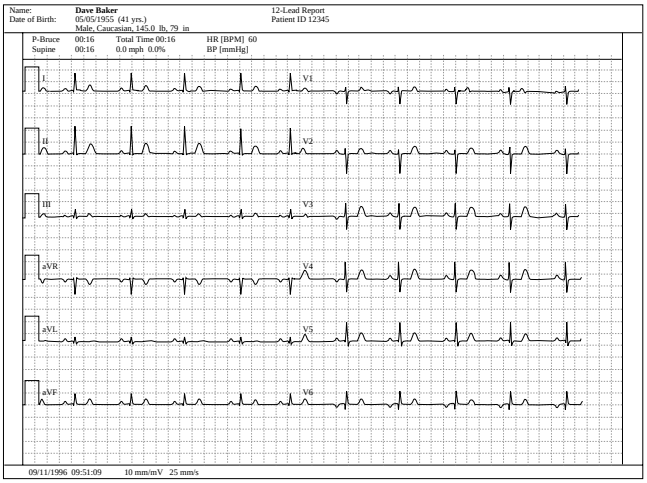


Figure 4.2-22. 12-lead report (2 x 5 s)

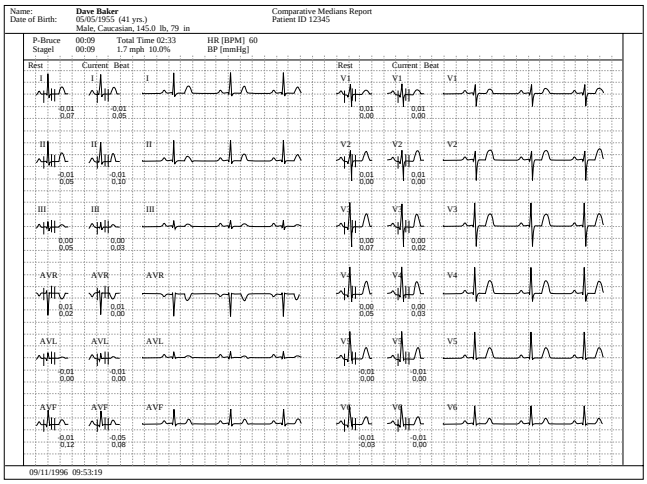

Name: Dave Baker
Date of Birth: 05/05/1955 (41 yrs.)
Male, Caucasian, 145.0 lb, 79 in
Comparative Medians Report
Patient ID 12345
P-Bruce 00:09 Total Time 02:33 HR [BPM] 60
Stage1 00:09 1.7 mph 10.0% BP [mmHg]
Rest
Current Beat
09/11/1996 09:53:19

Figure 4.2-24. Comparative medians report

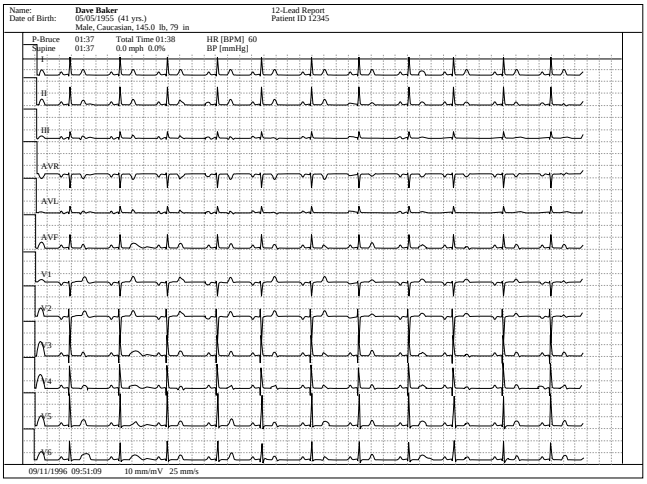


Figure 4.2-23. 12-lead report (1 x 5 s, the system saves 1 x 5 s but prints 1 x 10 s)

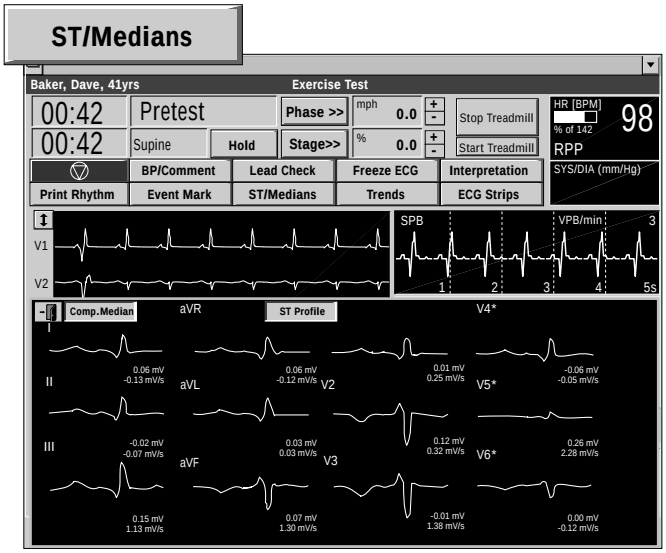


Figure 4.2-25. ST analysis results

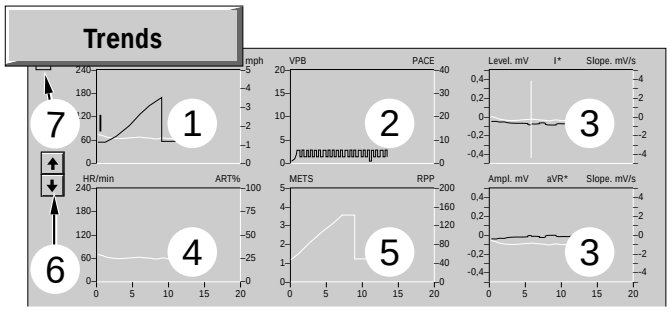


Figure 4.2-26. Graphic trends

1 *Heart rate, blood pressure, speed*
2 *VPB, pacer pulses*
3 *ST level/slope (slope and level of the 2 leads with the most significant ST changes, all other leads are accessible with button 6)*
4 *Heart rate, artifact*
5 *METS, RPP*
6 *Arrow buttons to call up the graphic ST trends of the other leads*
7 *Button to clear the trend window*

– review the ST analysis results (medians and profile) of all leads (Figure 4.2-25) with the **ST/Medians** buttons. The first screen shows the medians. With the **ST Profile** button you can toggle to the ST histogram screen (clear display with).

The **Comp. Median** or **Linked Median** button is displayed only when a thermal printer is connected to the system. The button actually shown depends on the system setup (section 4.2.7 “Exercise-Test Setup”).

The **Comp. Median** button initiates a printout showing:
– the resting beat for reference
– the current median complex
– a 2.5-second ECG segment
for all 12 leads.

The **Linked Median** button initiates a printout showing the current median complex and the corresponding RR interval linked by the computer to form a computer-synthesized rhythm strip for all 12 leads. The raw data of an additional rhythm lead are also printed for reference (this will be the first manually selected rhythm lead (item “Select Arrhythmia Lead” in the “Setup” menu)).

If the system is not able to analyze the ST segment, it will output the 12-lead report instead of the linked medians.

Click on to clear the ST screen.

– display trends (Figure 4.2-26) with the **Trends** button

> ***The displayed ST analysis results and graphic trends are updated every 30 seconds.***

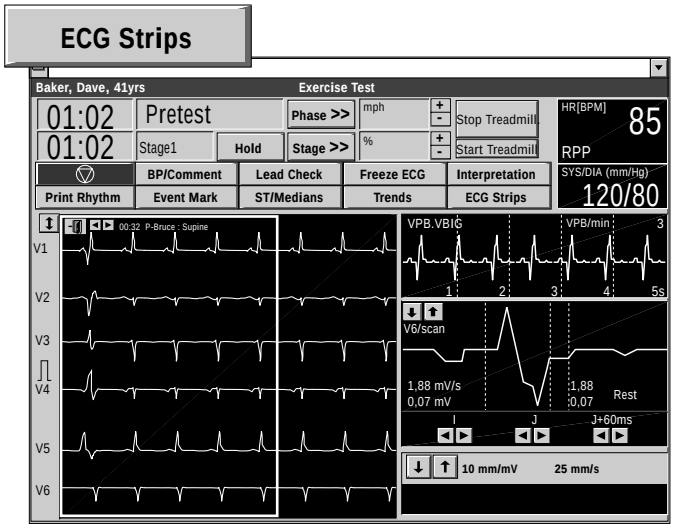


Figure 4.2-27. Stored 12 leads

– display segments of the stored 12 leads (Figure 4.2-27) with ECG Strips

The recordings are annotated with time and load. The first recording represents the 0 Watt level. With ◂ ▸ you can display the other recordings. The ◂| button allows you to access the current segment directly. Click on -| to clear the window.

Click on Interpretation

– to view the “Statement Library” page (refer to Figure 4.2-38).

– to select another test protocol. To do so, click on the label of the current test phase (“Pretest” in Figure 4.2-27) and choose the new protocol from the displayed list box. The program will switch to the new protocol when it proceeds to the next phase (this function is not possible with the following ergometer/treadmill selections (setup menu):
ERGA
intern., remote start
EC 1200

☞ ***The full-disclosure ECG takes up an enormous amount of the storage capacity, therefore delete it as soon as possible.***

☞ ***In the presence of complex ectopy it is advisable to record the full-disclosure ECG.***

METS Calculation

$$METS = \frac{(V\ [m/min] \cdot (0.1 + (grade\ [\%]/100) \cdot 1.8) + 3.5)}{3.5}$$

METS values are interpolated between two stages. The full METS value of a test stage is attained after the test subject has exercised for a period of 2 minutes in that stage.

Reviewing the Final Report

At the end of the test you will be informed whether complex ectopy has been identified and given the opportunity to delete or store the full-disclosure ECG.

If you made the recording without assigning it to a patient (Unnamed), you can enter a patient name now.

When you click on “Yes” or “No” the Test Summary will appear.

The complete exercise test report includes the following documents. They are described in detail on the following pages:

- Test Summary (Figure 4.2-28)
- Tabular Summary (Figure 4.2-31)
- Trend Reports (Figure 4.2-32)
- Sample Cardiac Cycles (Figure 4.2-34)
- QRS Morphologies (Figure 4.2-35)
- ECG strips (Figure 4.2-36)
- Arrhythmia Review (Figure 4.2-37)
- Interpretation (Figure 4.2-38)
- Full Disclosure ECG (Figure 4.2-39)

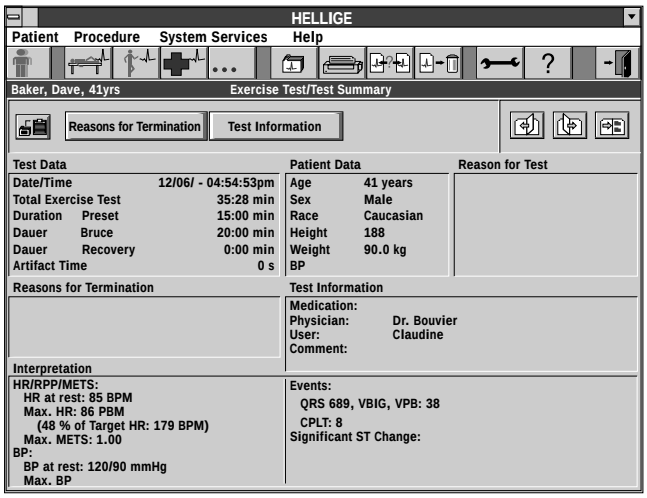


Figure 4.2-28. Test Summary

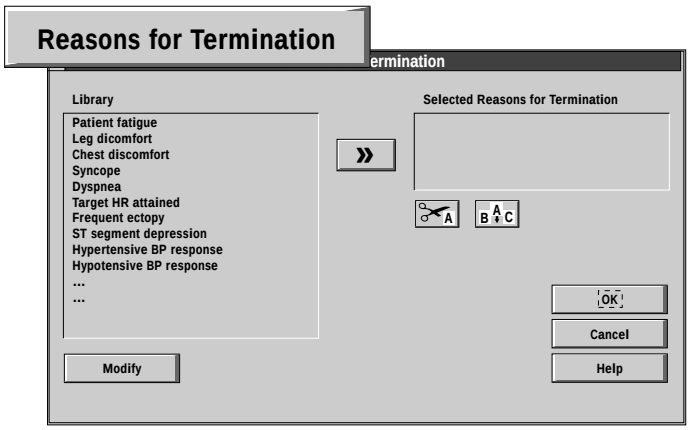


Figure 4.2-29. Reasons for Termination window

> ***Enter the reasons for termination in the same manner as the test information (section 4.2.3 "Entering the Test Information").***

The Test Summary

The Test Summary (Figure 4.2-28) includes:

- the test data (date, time, test duration)
- the patient data
- the test information
- the interpretation

A window in the middle is provided for entry of the reasons for terminating the test.

Click on **Reasons for Termination**. This brings up a window where you select the reasons by clicking (Figure 4.2-29).

If you have entered the test information as described in section 4.2.3 "Entering the Test Information ", these will be shown here along with the reason for test. If required, they can be modified.

To do so, click on the **Test Information** button.

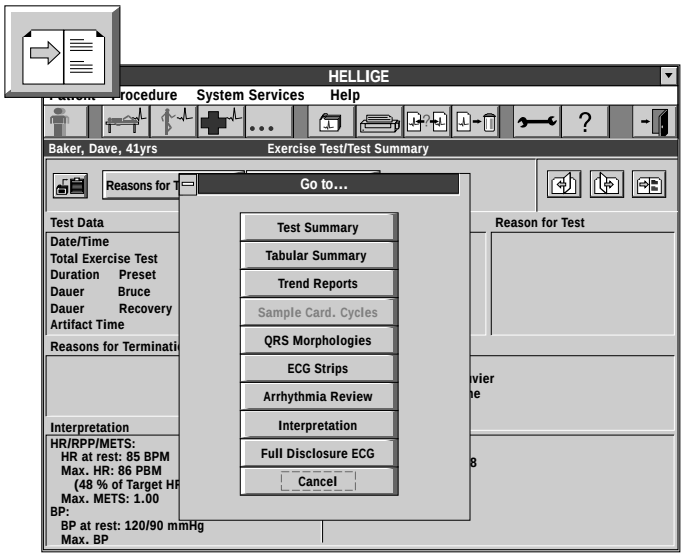


Figure 4.2-30. Documents of the exercise test report

Data Export

Using the export function you can save the relevant test data to the clipboard or to a file. When data are saved to the clipboard, they can be inserted in a text file, for instance.

- Click on .
- Select either “Export data to clipboard” or “Export data to file”.
- Select OK to confirm your choice.

When you export the data to the clipboard, you can insert them in a text file for further editing (commands “Edit” —> “Paste”).

If you choose the second option you will have to specify the directory and the file name. Confirm the export command with OK.

Displaying the Report Pages

You can either scroll through the entire final report, or access specific pages directly.

- Click on to scroll forward or on to scroll backward through the report pages.
- Click on to display the table of contents where you can select a specific document for review (Figure 4.2-30).
- Click on the title of the document you wish to display.

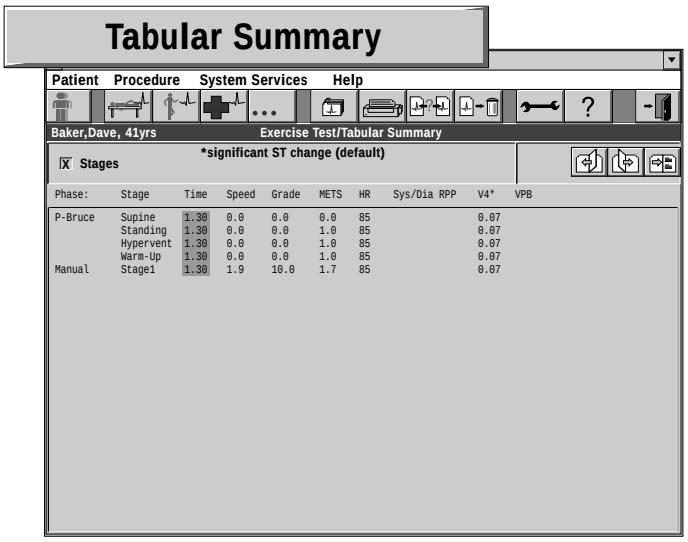

Tabular Summary
Patient Procedure System Services Help
Baker,Dave, 41yrs
Exercise Test/Tabular Summary
Stages
*significant ST change (default)
Phase: Stage Time Speed Grade METS HR Sys/Dia RPP V4* VPB
P-Bruce Supine 1.30 0.0 0.0 0.0 85 0.07
Standing 1.30 0.0 0.0 1.0 85 0.07
Hypervent 1.30 0.0 0.0 1.0 85 0.07
Warm-Up 1.30 0.0 0.0 1.0 85 0.07
Manual Stage1 1.30 1.9 10.0 1.7 85 0.07

Figure 4.2-31. Summary Table for treadmill test

> ***Only the stage format of the Tabular Summary is transmitted to MUSE.***

The Tabular Summary

For each stage of the test the tabular summary (Figure 4.2-31) shows:

Bicycle Ergometer	Treadmill
– phase	– phase/stage
– time	– time
– load	– speed
– RPM	– grade
– heart rate	– METS
– blood pressure	– heart rate
– RPP	– blood pressure
– ST level	– RPP
– number of VPBs	– ST level
– comments, if entered	– number of VPBs
	– comments, if entered

If the data in the table are to represent intervals of 30 seconds instead of test stages, uncheck the “Stages” check box.

Click on the arrows at the top and bottom of the scroll bar to scroll the lines one by one (Figure 4.2-31), or drag the scroll box up and down to cover greater distances and scroll to specific data.

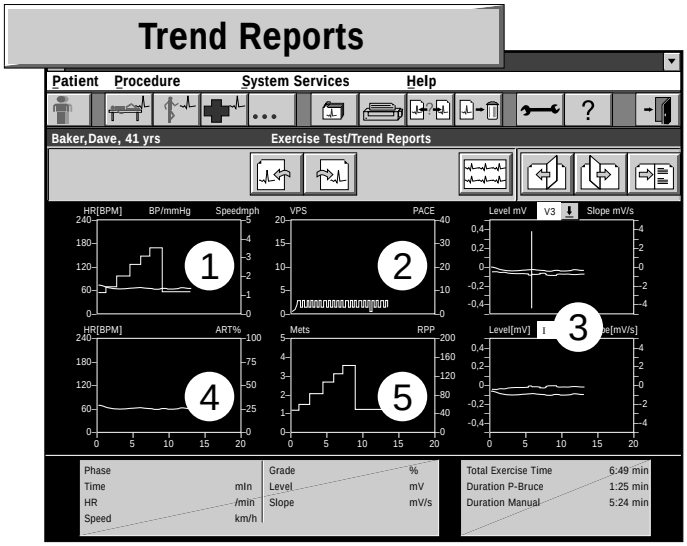


Figure 4.2-32. Trend Reports, page 1

The Trend Reports

Figure 4.2-32 shows page 1 of the trend reports. Here you see heart rate, blood pressure and speed (1)
VPBs and pacer pulses (2)
ST amplitude and slope (of the two leads with the most significant ST changes) (3)
heart rate and artifacts (4)
METS and RPP (5)

The program will show you the exact values for any point on the trend graph. When, in the selected trend period, the system could measure neither ST level nor slope, both values are set to zero.

Move the cursor which turns into a cross to the region of interest on the trace and click.

A vertical time line appears. The values corresponding to this point in time are displayed in the bottom part of the screen. As soon as you select another point on any of the trend curves, the old time line disappears and a new one is displayed. The bottom line shows comments that you have entered at the selected time. When no comment exists for the new selected time, the previous one is displayed.

With the icon, you can cross-reference to the segment of the full-disclosure ECG which corresponds to the position of the time line on the trend graph (with you can return to the trend graphs).

A dash in the upper margin of the trend windows indicates the change to the next test phase.

With and you scroll through the report. With and you scroll through the selected document of the report.

The system automatically selects the leads with the most significant ST changes and labels them with an asterisk * (except leads I, aVR, aVL, V1 and V2). You are free, however, to select any other two leads (place cursor on arrow, click and select lead). The leads that you select yourself do not have the *. The leads also appear in the Tabular Summary.

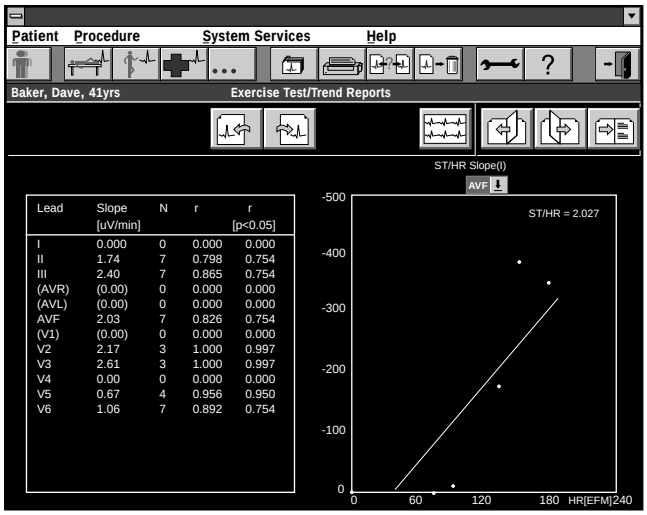


Figure 4.2-33. ST/HR slope according to R.J. LINDEN

Click or to display the other trend graphs. They show the ST trends from all recorded leads.

There is a total of three graphic trend reports. Page number 4 shows the ST/HR slope according to R.J. LINDEN (Figure 4.2-33).

Here you will automatically see the lead with the most significant slope (except leads I, aVR, aVL, V1). The graph indicates:

– the slope

– the number of points (N)

– the correlation quotient r

– the correlation quotient r for $p < 0.05$ (error probability less than 5%).

For details on the ST/HR slope, please refer to section 7.4 in the Appendix.

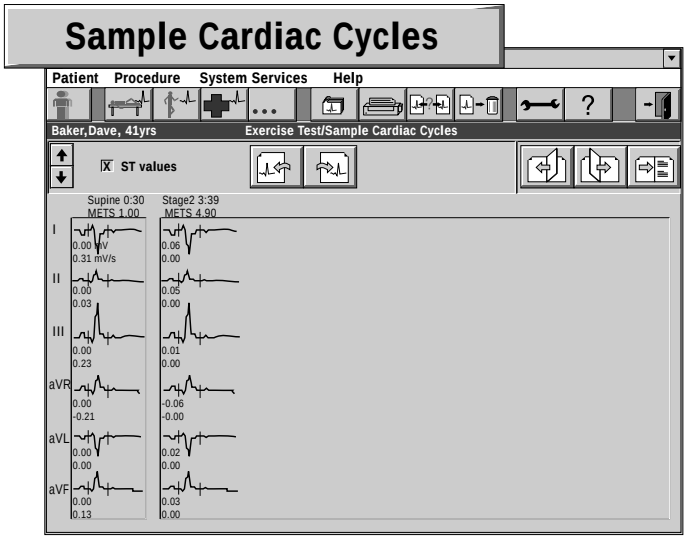


Figure 4.2-34. Sample Cardiac Cycles, page 1

Sample Cardiac Cycles

The Sample Cardiac Cycles page presents the median beats including the ST measurement points and ST results. Up to 6 leads are displayed per screen. The beats on the far left are the QRS complexes at rest, those following to the right are the median beats for each load stage (Figure 4.2-34). The program can display up to 20 median beats. When this number is reached, the program proceeds as follows: The beat on the far left is retained, while the latest beat overwrites the oldest beat in the section on the right. The last beat before a phase change is not overwritten.

Click ↑ or ↓ to display the next set of 6 leads.

Click ⇦ or ⇨ to move to the next or to the previous load stage.

With the check box next to “ST values” you can select ☒ or deselect ☐ display of the ST values.

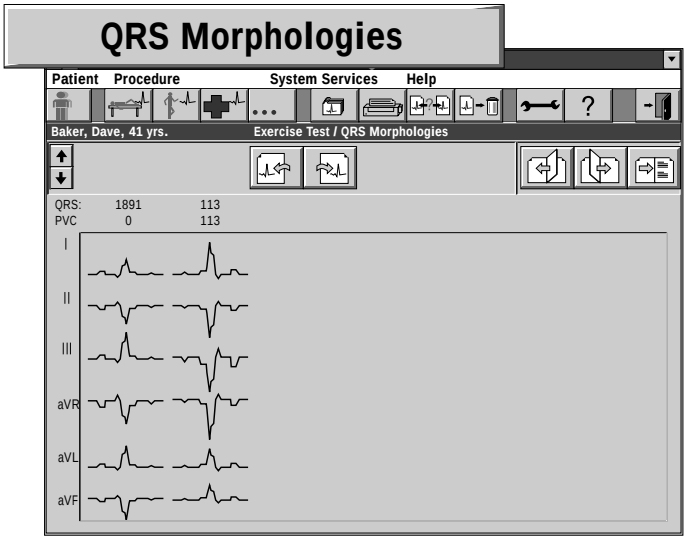


Figure 4.2-35. QRS Morphologies

QRS Morphologies

The system can save up to 10 different QRS templates and display them in all acquired leads. If more than 10 templates are encountered in the course of an exercise test the oldest one which occurred infrequently will be overwritten (Figure 4.2-35). Above each template, the display shows the overall number of beats belonging to that category (incl. PVCs). The number below indicates the PVCs only.

Use and to shift the columns to the right and left.

Use and to display the other leads of the same templates.

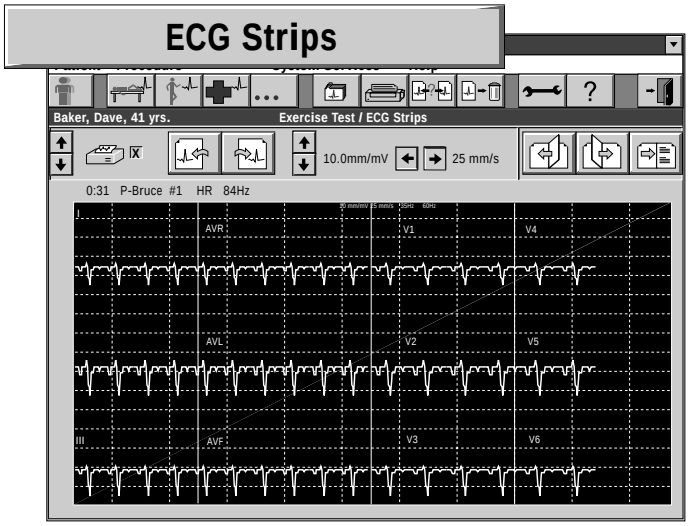


Figure 4.2-36. ECG recordings, 4 x 2.5 s

ECG Strips

This document shows the ECG traces as recorded with the selected recording interval or with the setting at the ergometer. Up to 30 ECG strips may be recorded. The data above the ECG are the corresponding workload and recording time. The print formats (4 x 2.5 s, 2 x 5 s, 1 x 5 s) are selected on the defaults screen. The format 1 x 5 s consists of two windows showing two recordings side by side. Formats 2 x 5 s and 4 x 2.5 s (cont.) consist of only one recording.

The check box next to the printer icon indicates whether or not the ECG strip will be printed later on. The default setting is [X].

Click on [X] to deselect the printout ([X] ECG printout, [ ] no ECG printout).

You can perform measurements on the recorded ECG as described in section 4.1.5.

Use [ ] and [ ] to display the next or the previous recording.

Use [↑] and [↓] to change the signal size and [←] and [→] to change the sweep.

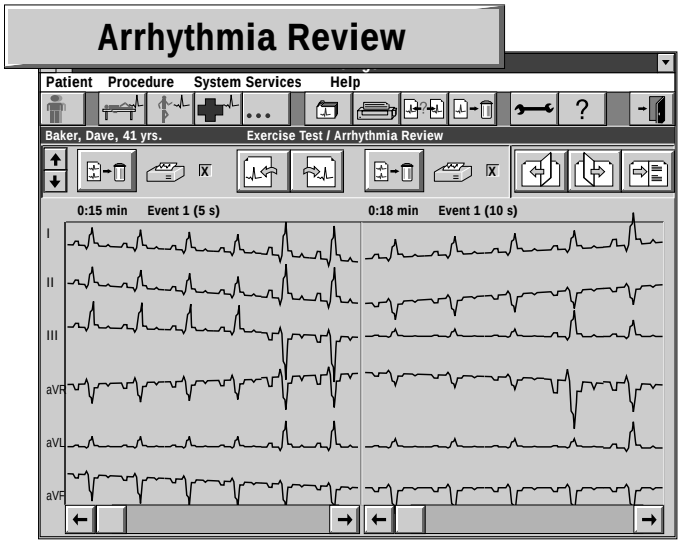


Figure 4.2-37. Arrhythmia Review

Arrhythmic Events (acc. to priority)		
– learned QRS complex	QRSL	
– asystole, limit value	ASYSTO	complex ectopy
– ventricular fibrillation/flutter	VFIB	complex ectopy
– ventricular tachycardia (>3 VPBs)	VTAC	complex ectopy
– ventricular run (3 VPBs)	RUN	complex ectopy
– ventricular couplet (2 VPBs)	CPLT	complex ectopy
– pause of 2 missed beats	PAU2	
– pause of 1 missed beat	PAU1	
– ventricular bigeminy	VBIG	
– pacer error	PERR	
– ventricular escape beat	ESC	
– premature ventricular contraction	PVC	
– pacemaker capture	PCAP	
– absolute pause, limit value	PAUA	
– artifact*	A	
– learn phase*	L	

* not on the event window and no episodes (full-disclosure ECG only)

Arrhythmia Review

If one of the events listed in the table on the left occurs during the test, the program records and saves a 5-second ECG episode. If multiple events occur, this period extends by 5 seconds for each event. Furthermore, a 10-second episode is recorded, when you press the Event Mark button during the test. The duration of an episode is also indicated.

The system can save up to 20 episodes of 5 seconds each (Figure 4.2-37). When the memory is full, the system decides which episodes to overwrite, observing certain priorities.

Use and to display the next two event episodes.

Click on to delete an episode.

Use and to display the other leads of the recordings.

Click on to deselect the printout (ECG printout, no ECG printout).

You can perform measurements on the ECGs as described for the “ECG Strips”.

> ***Manually stored event episodes always have the highest priority.***

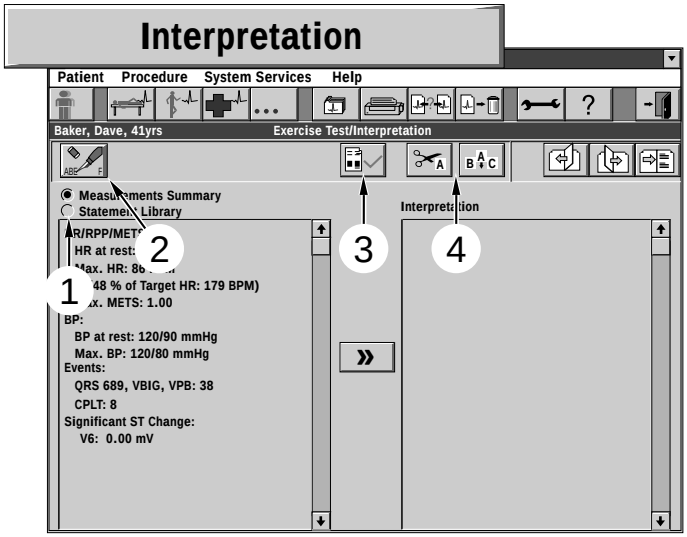


Figure 4.2-38. Interpretation

1 *Selection of system-generated measurements or statement library*
2 *Button to edit the statement library*
3 *Button to confirm interpretative statements*
4 *Buttons to edit the report*

If your PC is equipped with a sound card and a microphone, the program supports voice recording.

Interpretation

In order to generate the physician's interpretation of the test procedure you can choose both from the system-generated measurements and from the statement library which you entered yourself.

You can copy statements from both libraries by clicking on the respective lines and on the copy icon [»].

Select "System Evaluation" or "Statement Library".

Highlight the phrase you wish to copy, then click the [»] button.

Copy a line by just double-clicking on it!

Confirming Tests

A test is considered confirmed, when a physician has reviewed the test interpretation and "signed" it electronically with his/her name. Tests that have been reviewed and confirmed by a physician are marked with x.

Click on [✓] to display the window where you can enter your name (3, Figure 4.2-38).

Select the physician's name from the list box (click on [↓]) or enter it via the keyboard.

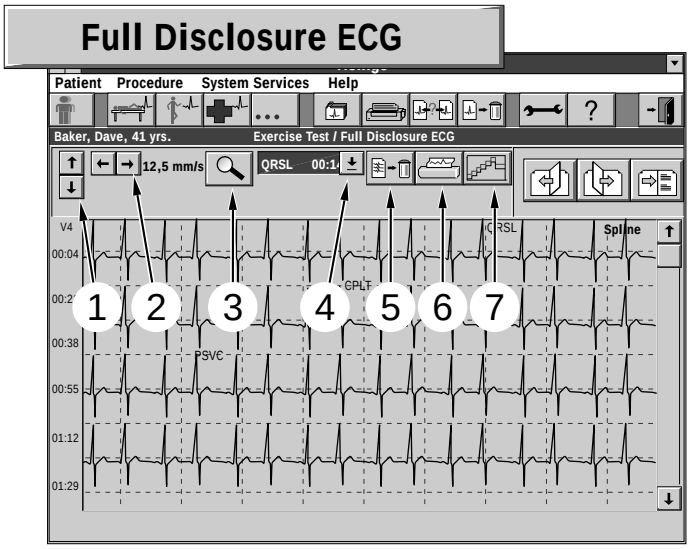


Figure 4.2-39. Full Disclosure ECG

1 *Buttons to call up additional leads*
2 *Buttons to select the sweep speed*
3 *Button to activate the zoom function*
4 *Button opening the event selection window*
5 *Button to delete the full disclosure ECG*
6 *Button to print out a trace segment*
7 *Button to cross-reference to the trend display*

> ***Typing the first letter of an event (e.g. "P" for PVCs) takes you from one occurrence of this event to the next.***

Full Disclosure ECG

Each lead of the stored 3, 6 or12-channel full disclosure ECG can be displayed. The events identified by the rhythm analysis algorithm are highlighted. The times are shown in the left margin (Figure 4.2-39).

You can choose between perusing the entire recording (by dragging the scroll box in the scroll bar at the right), jumping from one event to the next (with the cursor keys), and selecting a specific event category from the event list (button (4) Figure 4.2-39). You can also zoom important sections of the ECG and save them as episodes. This allows you to pick particularly interesting segments from the full disclosure ECG and save them, discarding the rest, because it takes up too much storage capacity (button).

Furthermore you can mark segments of special interest and print them out:

- Click on the beginning of the trace segment (which will then be marked by a flag).
- Click on the end of the trace segment (which will also be marked by a flag).
- A printout of the segment is obtained by clicking on .
- Click on if you wish to return to the trend display.

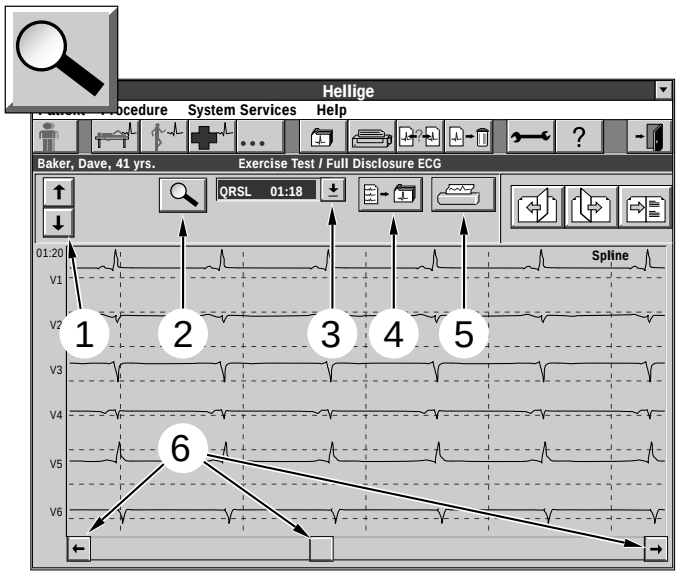


Figure 4.2-40. Display of a zoomed segment

1 *Buttons to display the other leads of the same segment*
2 *Button to quit the zoomed segment and return to the full disclosure ECG*
3 *Button to open the event selection window*
4 *Button to save the segment as an episode*
5 *Button to print the zoomed segment*
6 *Buttons to display another time window*

☞ ***On the zoomed display the ECG is shown with 4 times the original speed.***

☞ ***Manually stored event episodes always have the highest priority.***

Displaying Zoomed Segments

You can choose regions of special interest and display them at a larger scale. Here too you can jump from one event to the next.

Click (Figure 4.2-39).

Move the cursor which turns into a magnifying glass to the trace segment of interest and click. Figure 4.2-40 will appear.

The cursor keys will take you to the neighboring episode (before or after the present one).

If you drag the scroll box (6), you can quickly select any segment of the entire ECG.

The button allows you to save the segment as an event episode.

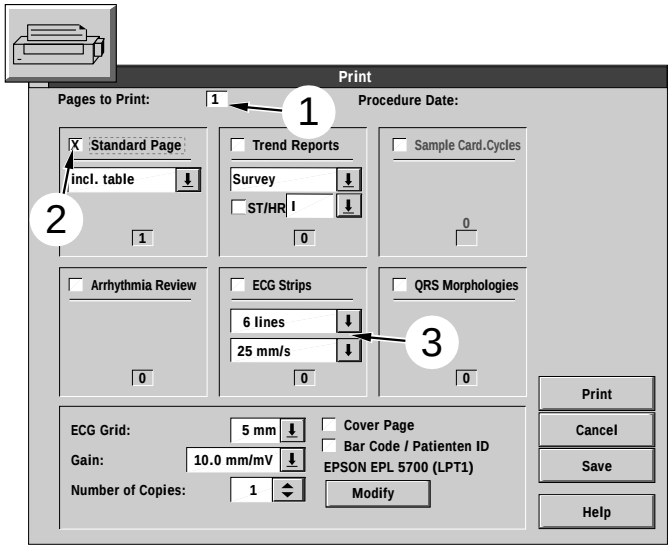


Figure 4.2-41. Exercise ECG print setup screen

1 Number of pages of the entire report

2 Document selected for printout

3 Dialog boxes appear only when "1 x 5s" has been selected in the "In-Test Report" menu

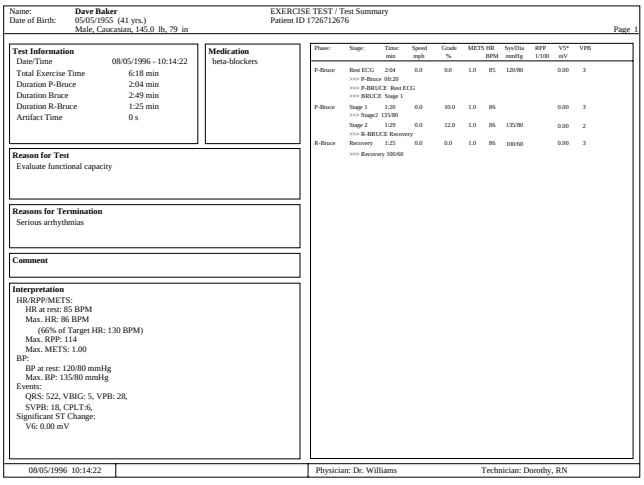

Name: Dave Baker
Date of Birth: 05/05/1955 (41 yrs.)
Male, Caucasian, 145.0 lb, 79 in
EXERCISE TEST / Test Summary
Patient ID 1726712676
Page 1
Test Information
Date/Time 08/05/1996 - 10:14:22
Total Exercise Time 6:18 min
Duration P-Bruce 2:04 min
Duration Bruce 2:49 min
Duration R-Bruce 1:25 min
Artifact Time 0 s
Medication
beta-blockers
Reason for Test
Evaluate functional capacity
Reasons for Termination
Serious arrhythmias
Comment
Interpretation
HR/RPP/METS:
HR at rest: 85 BPM
Max. HR: 86 BPM
(66% of Target HR: 130 BPM)
Max. RPP: 114
Max. METS: 1.00
BP:
BP at rest: 120/80 mmHg
Max. BP: 135/80 mmHg
Events:
QRS: 522, VBIG: 5, VPB: 28,
SVPB: 18, CPLT-6,
Significant ST Change:
V6: 0.00 mV
Phase: Stage: Time: min Speed mph Grade % METS HR BPM Sys/Dia mmHg RPP 1/100 V5* mV VPB
P-Bruce Rest ECG 2:04 0.0 0.0 1.0 85 120/80 0.00 3
>>> P-Bruce 00:20
>>> P-BRUCE Rest ECG
>>> BRUCE Stage 1
P-Bruce Stage 1 1:20 0.0 10.0 1.0 86 0.00 3
>>> Stage2 135/80
Stage 2 1:29 0.0 12.0 1.0 86 135/80 0.00 2
>>> R-BRUCE Recovery
R-Bruce Recovery 1:25 0.0 0.0 1.0 86 100/60 0.00 3
>>> Recovery 100/60
08/05/1996 10:14:22
Physician: Dr. Williams
Technician: Dorothy, RN

Figure 4.2-42. Standard page

4.2.5 Printing an Exercise-Test Report

The scope of the printed report is determined on the print setup screen (Figure 4.2-41).

Click to call up the print setup screen.

The report includes the following sections:

- Standard Page
- Trend Reports
- Sample Cardiac Cycles
- Arrhythmia Review
- ECG Strips
- QRS Morphologies

Clicking the box in front of each of these documents includes them in or excludes them from the report (check mark = included). The length of each document and of the overall report is also indicated.

Print initiates the printout.

Save stores the print setup so that the next time the screen is retrieved the settings will be the same.

Standard Page

The standard page (Figure 4.2-42) shows, at left, the patient data, reason for test, reasons for termination, medication, comments and ECG interpretation. The right side of the page shows either the table of all measured data or the ST beats, as selected.

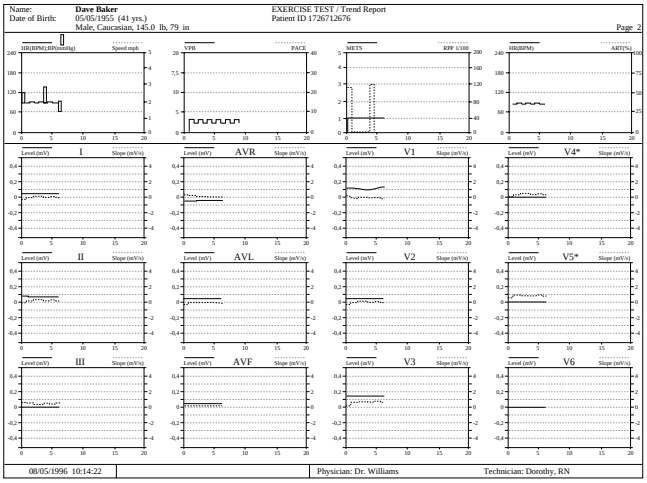


Figure 4.2-43. Trend report – overview

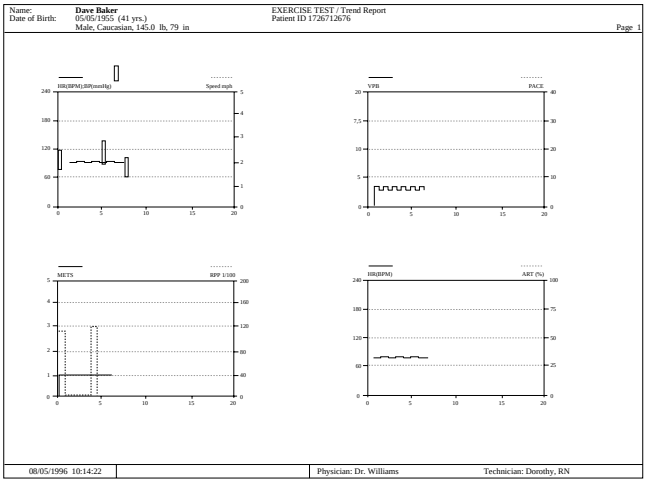


Figure 4.2-44. Trend report – detailed format

The ST beats page shows the resting ST beats in the first column, the ST beats with the max. ST depression in column no. 2 and in the following columns the ST beats at max. load and for the recovery phase.

Trend Reports

You can choose between “Overview” and “Detail”. In the overview (Figure 4.2-43), all trend graphs are printed on a single page. When you select “Detail”, you obtain several pages of trend graphs (Figure 4.2-44). The number of pages to be printed changes accordingly. (Click and select format). Check the ST/HR box to obtain a printout of the ST/HR slope page.

Arrhythmias, Full Disclosure ECG (Recording Interval), QRS Morphologies, Sample Cardiac Cycles

You can choose the documents (Figures 4.2-45 trough 4.2-48) that you want to print, and you determine whether you wish to have a 12 or 6-channel recording (window below).

In the windows at the bottom of the screen you select the printer (printer port), the number of copies, whether the patient ID no. will be annotated in the form of a barcode on the report and whether an ECG grid is to be printed along with the ECG traces. If you deselect the grid, the printout will take less time.

Cover Page

Check to print a cover page in portrait format.

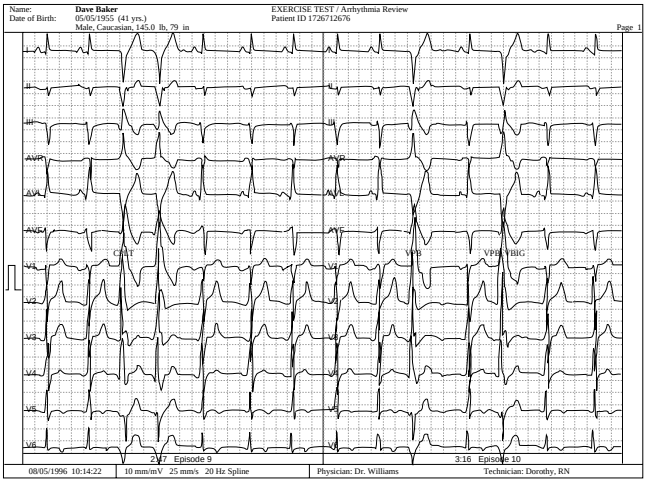


Figure 4.2-45. Arrhythmia review report page

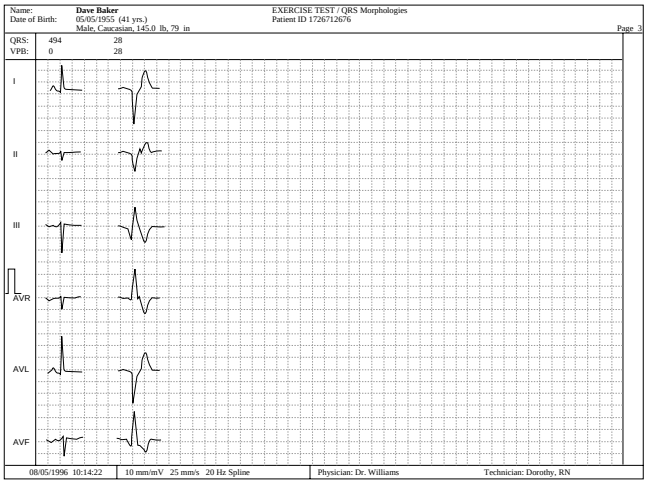


Figure 4.2-47. QRS morphologies report page

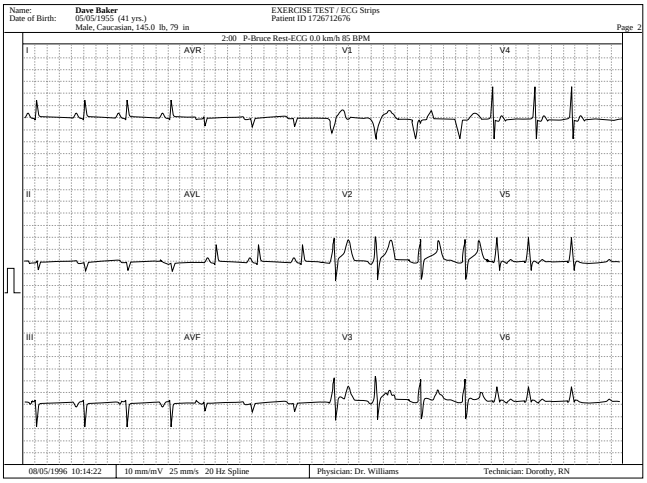


Figure 4.2-46. ECG Strips report page

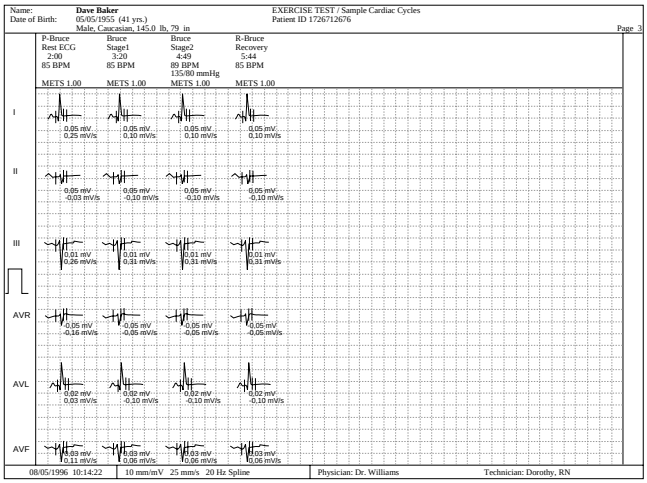


Figure 4.2-48. Sample cardiac cycles report page

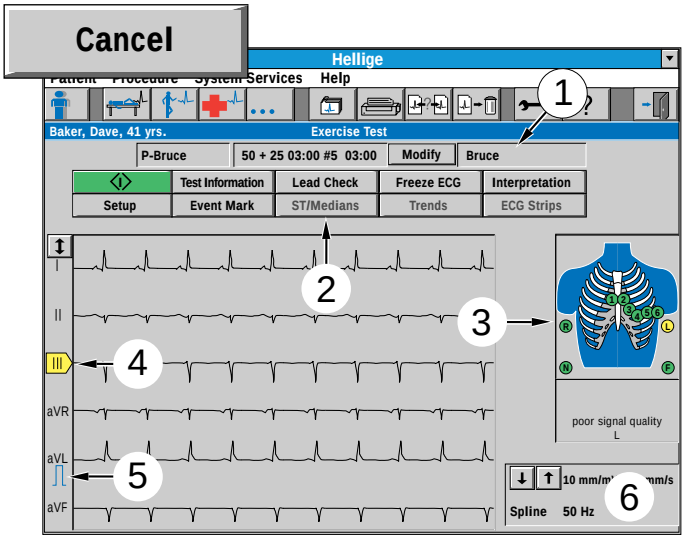


Figure 4.2-49. Exercise-test control screen

1 *Selected protocol*
2 *Control buttons*
3 *Applied electrodes*
green: properly applied
yellow: poor signal
red: electrode off or lead break
white: electrode not used
4 *Leads impaired by poor signal quality*
5 *Calibration pulse*
6 *System settings*

4.2.6 Verifying the Exercise-Test Settings

Clear the test information dialog window with **Cancel** to display the exercise-test control screen.

The control screen (Figure 4.2-49) shows:

– the selected protocol (1)

– the applied electrodes and the signal quality (3) (for the standard and CABRERA leads on the body as shown on the picture at left, for all other leads, there is a schematic representation of the electrodes). Furthermore an arrow (4) points to the leads which are impaired by improper electrode application or which cannot be recorded due to disconnected electrodes (or due to a break in the patient cable)

– the selected gain (the 1-mV calibration pulse (5) is valid for all channels)

– the most important system settings (6).

Other operations possible on the control screen are

– temporary modification of the test phase with **Modify...** (enter the test information before changing the phase, otherwise the changes will be lost)

– verification of the ECG signal quality with **Lead Check**

– display of the setup menu (section 4.2.7) with **Setup**

System settings and operating steps are explained on the following pages.

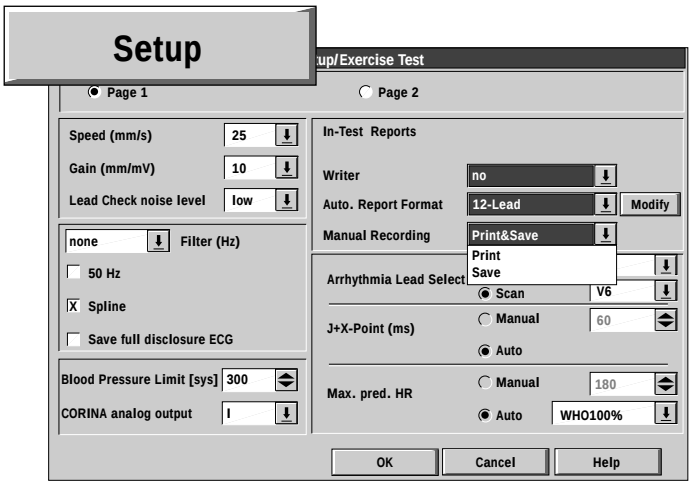


Figure 4.2-50. Exercise-Test Setup, page 1

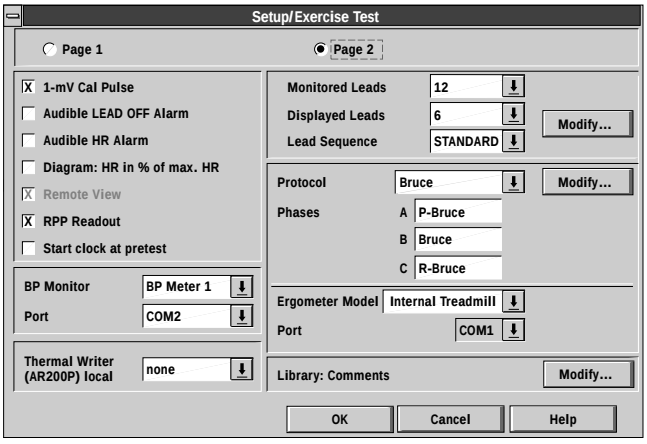


Figure 4.2-51. Exercise-Test Setup, page 2

4.2.7 Exercise-Test Setup

Before running the first stress test, select several system settings on the setup screen. These settings are saved and loaded automatically on power up. The setup menu is displayed from the exercise-test control screen (section 4.2.6).

Select [Setup] to display page 1 of the menu (Figure 4.2-50).

Adjustments can be made in four different ways:

1 There is an arrow ↓ at the end of a box. Clicking this arrow will open a window which offers various options. Select the desired setting by clicking the mouse button.

2 There is a two-ended arrow ⇕ to the right of a box. Clicking one of the arrowheads increases or decreases a numeric value.

3 There is a check box in front of the function. Click on the box to enable or disable the function (☒ function enabled).

4 Click on the [Modify...] box and proceed as described for each individual case.

Page 1 (Figure 4.2-50)

Speed mm/s
selects the trace sweep speed.

Gain mm/mV
selects the signal size (amplitude).

Lead Check noise level
This is a measure of the quality of the acquired signal (signal to noise ratio). When there is too much signal noise at the electrode, the electrode is displayed yellow on the signal acquisition screen. The setting that you select here (low, middle, high) changes the threshold as of which the electrode is displayed yellow (high sensitivity to noise = low threshold).

> ☞ ***Please remember that a filter may also suppress diagnostically relevant information, as it limits the frequency bandwidth. Therefore you should not switch the filters on indiscriminately.***

Filter
Enables or disables muscle filter (none, 20 Hz, 40 Hz)

50/60-Hz Filter
Enables or disables AC filter (☒ AC filter on)

Spline
Enables or disables the Cubic Spline algorithm (automatic baseline correction, ☒ Spline on); the algorithm causes a signal delay of 4 seconds. On the signal acquisition and control screen the algorithm can be disabled temporarily to view the undelayed ECG signal.

Save full disclosure ECG
Enables or disables continuous storage of the incoming ECG which can be edited retrospectively and deleted, for instance to save storage capacity. The max. storage time is 30 minutes.

Blood Pressure Limit (sys)
Here you enter the max. systolic blood pressure. When, during the test, the blood pressure exceeds this value, the pressure reading is highlighted with a different color.

CORINA analog output
To select the lead for the analog output

In-Test Reports
Here you select the printer for reports generated during the test (in-test reports). You can choose among thermal-array writer, laser printer and no printer. For the thermal writer, you can specify and create your own automatic report format ([Modify...] button).
This button brings up a window where you choose the format of the 12-lead report (4 x 2.5 s, 2 x 5 s, 1 x 5 s). The format selected here also determines the way the “ECG Strips” report page is presented.
With “Recall” and “Rhythm” you determine the report format of the printouts initiated with the [Recall] and [Rhythm] buttons (section 4.2.4 “Running an Exercise Test”). The menu item “Median Report” allows you to choose whether the comparative medians or the linked medians will be printed.

Auto. Report Format

Here you select the report generated at the selected recording interval: 12 lead or comparative medians (possible only with the thermal writer).

Manual Recording

Here you choose whether a manual recording will be

– printed,
– saved, or
– printed and saved.

Arrhythmia Lead Select

The two leads used for arrhythmia analysis are selected either by the system (Scan) or by the user (Manual).
The first of the manually selected leads will be added to the linked medians report as the rhythm lead. To change the lead select “Manual” and choose the lead. Afterwards you may reactivate the “Scan” mode.

J+X Point

The measurement point J+X for ST analysis may be determined by the program or manually by the user.With “manual”, you can make a preliminary adjustment of the J+X point on this screen and then shift the E, J and J+X points during the exercise test. In the automatic mode, the J+X point is calculated in dependence of the heart rate (for HR of 60 BPM, X=60 ms, X becomes smaller with increasing heart rates). For calcuation of the ST/HR slope, the “manual” method must be selected and the reference point should be set at J + 60 ms.

HR Limit

The max. heart rate is either entered by the user or calculated automatically by the program.
The automatic calculation is performed according to one of the following rules:

– WHO 80 (max. HR = 180 – age)
– WHO 90 (max. HR = 200 – age)
– WHO 100 (max. HR = 220 – age)
– AHA (max. HR = 160 (for patients under 25 years of age) or 115 (for patient over 75 years of age) or 160 – ((age – 25) x 45/50) (for patients between 25 and 75 years of age)

We recommend using WHO 100 and modifying the target HR on the test demographics screen, if required.

Page 2 (Figure 4.2-51)

1-mV Cal Pulse
Display of 1-mV calibration pulse: yes or no (☒ yes)

Audible LEAD OFF Alarm
Audible signal when an electrode is disconnected: yes or no (☒ yes)

Audible HR Alarm
Audible signal when heart rate limit is exceeded: yes or no (☒ yes)

Diagram: HR in % of max. HR
Do you wish to have this diagram displayed on the exercise-test screen (section 4.2.4 “Running an Exercise Test”)?

Remote View
Enables or disables transfer of the procedure data from a remote exercise-test station to the local station (section 4.2.8 “Monitoring Remote Exercise-Test Workstations”).

RPP Readout
Display of the RPP (rate pressure product)? Select or deselect.

Start clock at pretest
Check this box if you want the clock to start with the pretest phase.

BP Monitor
For selection of BP monitor to be used:
- no: no blood-pressure monitor available (you will be asked to take the blood pressure manually)
- in ergometer: a monitor is integrated in the ergometer
- BP Meter 1: the SunTech 4240 monitor is connected, in this case you have to select the interface (Port: COM1 through COM4).
- BP Meter 2: Marquette Hellige bosotron 2
- if your system is not equipped with a BP monitor and you do not wish to be prompted for a BP measurement, set the BP interval for all test stages in the list to “0”.

Thermal Writer
For selection of the interface where the thermal printer is connected (LPT1 through LPT4). After the configuration, restart the Windows program.

Monitored Leads
Allows you to select the number of leads to be monitored (3, 6, 12).

Displayed Leads
Allows you to select the number of leads to be displayed (3 or 6).

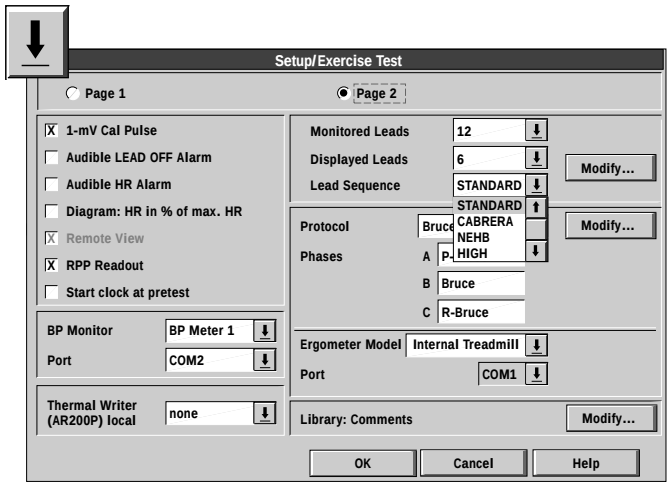


Figure 4.2-52. Lead sequence selection window

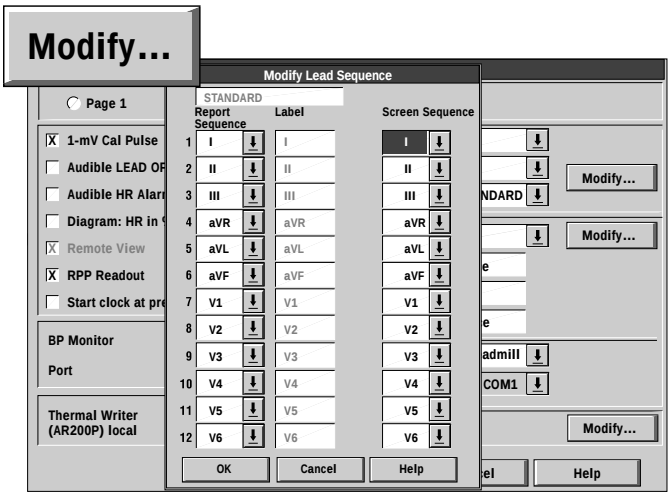


Figure 4.2-53. Modifying the lead sequence

Lead Sequence

The lead sequences change with the number of recorded channels (3, 6, or 12). You can choose from 6 different sequences. Two of these (sequence 1 and 2) are fixed. The others can be modified as follows (also you can differentiate between the sequence on screen and on the printout):

- Click the arrow ⬇ to the right of Lead Sequence to open the lead sequence window (Figure 4.2-52).
- Select the sequence that you wish to modify (any sequence, except 1 and 2).
- Select Modify....

A window opens showing all channels (Figure 4.2-53). There is one window for each of the channels indicating the lead currently assigned to that channel.

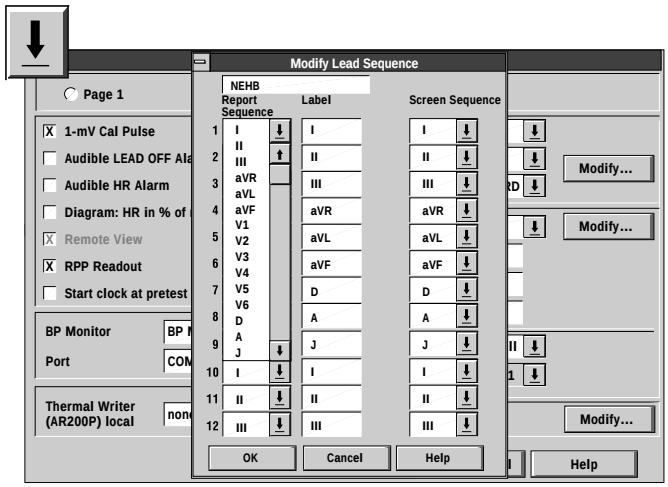


Figure 4.2-54. Modifying the lead sequence

Click the box or the arrow ⬇ to display all available leads (Figure 4.2-54).

Select the new lead to be recorded in the respective channel.

Enter up to 4 characters in the “Label” column to label the lead.

Once you have assigned a lead to each of the channels, you can enter a name for the lead sequence in the headline.

Move the cursor to the text box at the top and click.

Enter a name and click on OK to clear the window.

The “Print Sequence” column allows you to assign the acquired leads to the printer channels.

Protocol

A protocol comprises up to three phases. These are the pretest phase, the exercise phase and the recovery phase. The program comes with several preconfigured protocols for the various patient categories (for instance: BRUCE protocol). In the “Protocol” window you select the default protocol, specify a new protocol or modify existing protocols.

Click ⬇ to open the window, then select the protocol. The test phases of this protocol appear in boxes A, B, and C. This concludes selection of the default protocol.

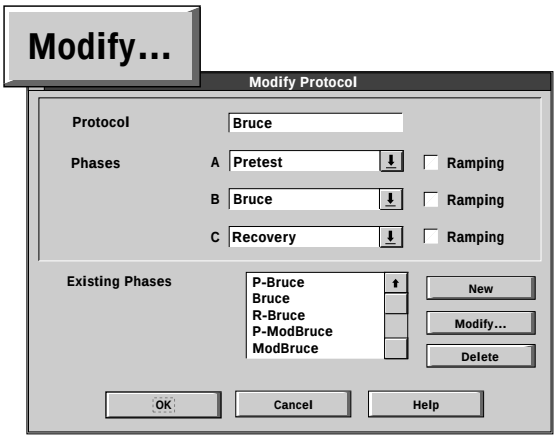


Figure 4.2-55. Protocol entry window

> ***The program can save up to 10 different test protocols.***

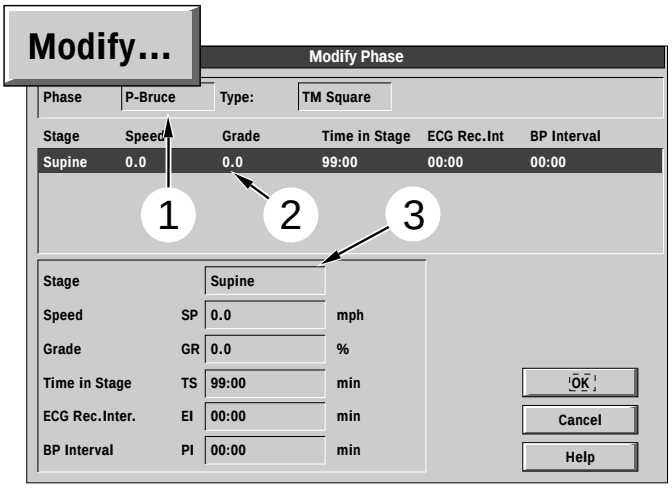


Figure 4.2-56. Window for definition of a test phase

1 Phase

2 Phase parameters

3 Entry boxes

Click [Modify...] if you wish to modify an existing protocol or to define a new one. This will open the entry window (Figure 4.2-55).

Click [↓] in the box for phase A, then select one of the phases in the window by clicking.

Select phases B and C in the same way.

Select “Ramping” if you wish the load to increase gradually over the specified time of the phase.

If you wish to modify specific parameters of one of the phases, or create a new phase, click [Modify...] or [New]. This will open the window allowing you to define a test phase (Figure 4.2-56).

Position the cursor on the parameter to be changed and click.

Enter the new value. It is possible to leave a box blank or to remove a parameter.

Modify the other parameters in the same way.

If you wish to create a new phase, enter a (new) name under which the phase will be saved.

Click on [OK] to clear the window.

A modified phase stored under a new name is not automatically included in a test protocol. For this, it must be selected from the list.

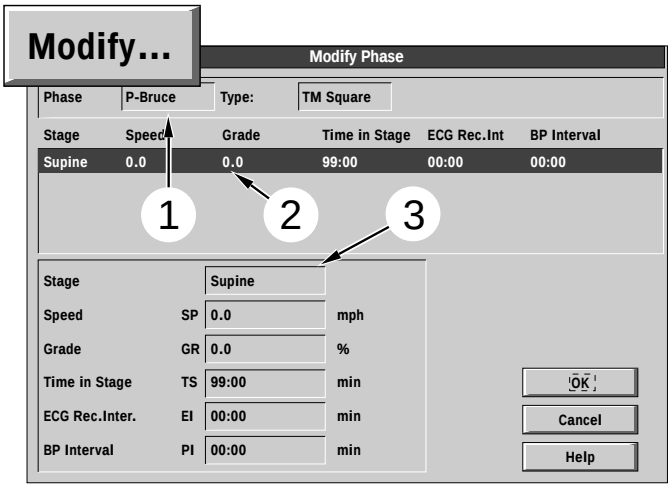


Figure 4.2-56. Window for definition of a test phase

1 Phase

2 Phase parameters

3 Entry boxes

Some of the test phases, such as WHO, cannot be modified. When you change any of its parameters you must save it under a new name.

Warning

Do not specify BP intervals < 2 min. This may result in wrong values and may damage the tissue.

The results of BP measurements that take longer than 60 s to complete are entered in the next line of the table. You can avoid this effect by selecting a shorter interval for the first BP measurement which will then start earlier.

Example: measurement duration 90 s
interval 3 min
1st BP interval 2:30 min

Modifying Square-Wave Tests

Click the stage to be modified (reverse video, 2, Figure 4.2-56). The corresponding values will be displayed at 3 (Figure 4.2-56).

Click the value to be modified and type the new value (you are free to leave entry boxes open and to delete values).

Having made all necessary changes, click OK to clear the window or click the next stage to be modified.

If you wish to add a stage, click ... below the last stage.

Enter the new values as described above.

Enter a name for the phase and click on OK to clear the window.

- A test stage suitable for inclusion in a test protocol must comprise the parameters speed, grade and stage time.
- You may add any number of stages that consist of a recording interval and a BP interval only.
- Stage names are adopted only when they include all required parameters.
- Up to 120 values can be entered, irrespective of the number of stages. Blank entry boxes will not be counted.

☞ ***If the basic load or load duration is missing for one of the square-wave or treadmill tests, the system will skip this stage during the actual stress test.***

– if your system is not equipped with a BP monitor and you do not wish to be prompted for a BP measurement, set the BP interval for all test stages in the list to “0”.

Ergometer/Treadmill
Allows you to select the ergometer/treadmill model used for the test.

Port
Allows you to select the communications port to which the ergometer/treadmill is connected (default: COM 2).

Comments Library
Here you may enter or modify comments to be added to the procedure “during the test” (section 4.2.4 “Running an Exerise Test”).

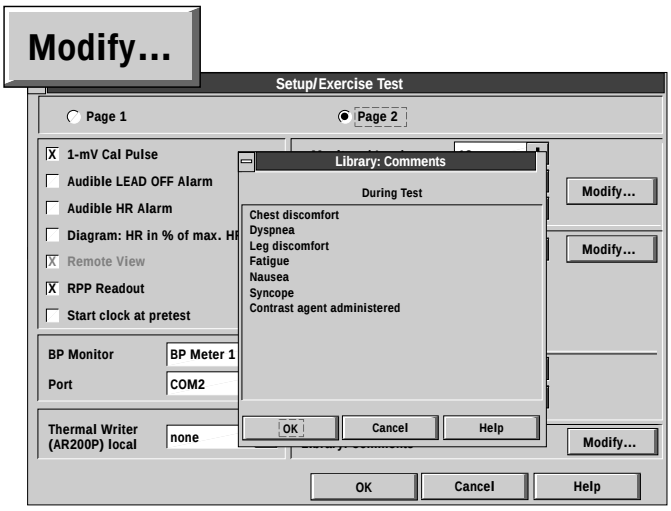


Figure 4.2-57. Standard comments entry window

Select [Modify...]: A window opens showing the library of existing comments (Figure 4.2-57).

Move the cursor to the item you wish to change and click.

Enter the modification.

Select [OK] to clear the window.

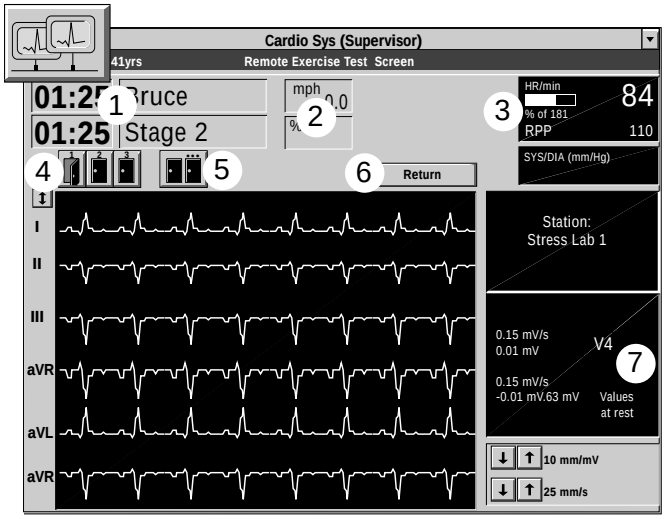


Figure 4.2-58. Monitoring of a remote exercise-test station

1 *Durations, phase name, stage number*
2 *Speed and grade*
3 *Heart rate, blood pressure, RPP*
4 *Key to call up further ECG leads*
5 *Buttons to call up further remote stress-test stations*
6 *Button to terminate the monitoring function*
7 *ST measurement results (resting beat, current beat)*

☞ ***Conditions for monitoring of remote exercise-test workstations are:***
- ***a station name was entered***
- ***the monitoring function is enabled***
- ***the correct communication protocol (netbios.exe or TCP/IP) is installed and selected (System Services –> System Configuration –> Remote Test Screen).***

4.2.8 Monitoring Remote Exercise-Test Workstations

The program allows you to monitor exercise tests at remote stations from your PC. Click to call up the monitoring screen (Figure 4.2-58). The function is available only when you have entered a station name in the system setup menu at both stations (section 6).

Click on [...] to display the procedure selection menu.

Select the remote exercise-test monitoring screen (button).

In the selection window, click the station you wish to monitor. Then click [OK] to clear the window.

The remote station screen is made up in the same way as the exercise-test acquisition screen: durations, phase name and stage number (1), speed and grade (2), heart rate, blood pressure (3), buttons to display more ECG leads (4), buttons for selection of other remote exercise-test stations (5) and the [Return ...] button which is used to quit the monitoring function (6).

☞ ***When data are lost while transferred via the network (slow PC), you will be alarmed by a red bar.***

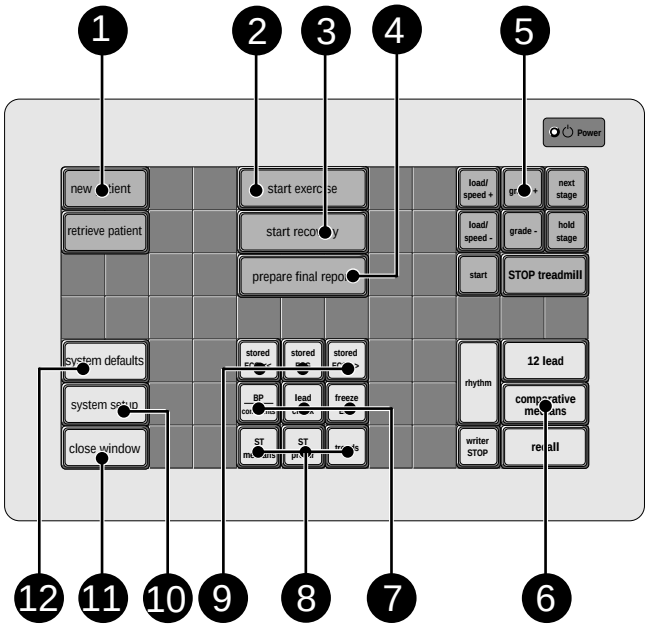


Figure 4.2-59. The function keypad

4.2.9 Using the Function Keypad

* Start the program.

* Press *new patient* or *retrieve patient* (1) and enter the patient data.

* Start the test with .

* Start the exercise phase with (2) *start exercise* and ask the patient to start pedalling or start the treadmill with *start* (5).

Now you can:

* Advance to the next stage (*next stage* (5)) or continue at the same stage (*hold stage* (5)).

* Start and stop the treadmill with *STOP treadmill* and *start* (5).

* Increase or decrease the speed (*load/speed* +/– (5)).

* Increase or decrease the elevation of the treadmill belt (*grade* +/– (5)).

* Display and review the ECG strips (*stored ECG* (9)). Press *close window* (11) to clear the window from the screen.

* Enter BP readings and comments (*BP/comments* (7)). Press *close window* (11) to clear the window from the screen.

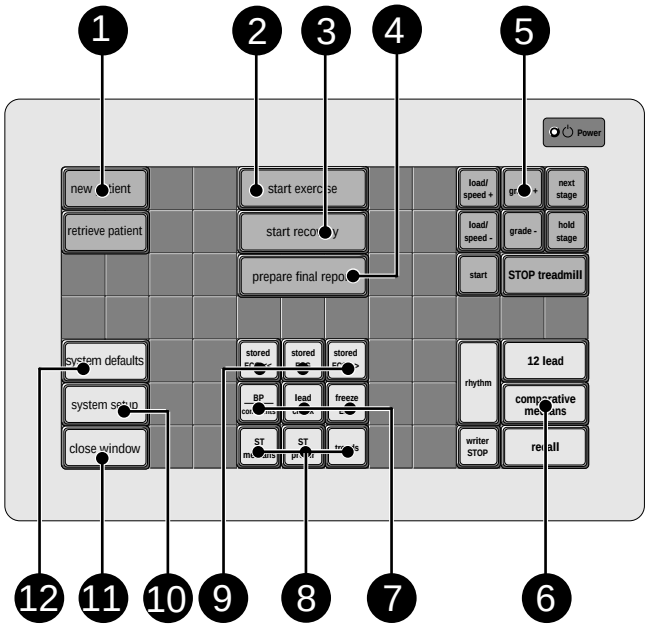


Figure 4.2-59. The function keypad (repeated)

* Check the ECG signal quality (*lead check* (7)). Press *close window* (11) to clear the window from the screen.

* Freeze and release the ECG signal traces with *freeze ECG* (7).

* Display the ST measurement results with *ST medians*, *ST profile* (8). Press *close window* (11) to clear the window from the screen.

* Display graphic trends with *trends* (8). Press *close window* (11) to clear the window from the screen.

* Start and stop the thermal-array printer with keys (6).

* Initiate the recovery phase with *start recovery* (3).

* End the exercise test with *prepare final report* (4).

4.2.10 Short-Form Operating Instructions

MEDITRONIC M 400

Start program

Call up the exercise-test screen

Admit new patient or select patient from list

Apply electrodes and check signal quality

Enter the test information

Select protocol

Adjust initial load at the ergometer as required by the selected protocol

Click button and wait for ST values to be displayed (option)

Click button and start pedalling

Repeat all load changes of the selected program at the ergometer

Selects the next stage

Maintains the stage

Modifies the load in 5-Watt increments

Selects the recovery phase

Quits program

MEDITRONIC M 40

Start program

Call up the exercise-test screen

Admit new patient or select patient from list

Apply electrodes and check signal quality

Enter the test information

Select protocol

Adjust initial load and load increase/stage as required by the protocol selected at the ergometer

Click button and wait for ST values to be displayed (option)

Click button and start pedalling

Interactive load changes (+5W) and adjustment of load for recovery phase

Modifies the load in 5-Watt increments

Selects the recovery phase

Quits program

ERGOCOMP EC 560/ECB 561, ERGOLINE 900/900L, EC 1200 V3.52

Start program

Call up the exercise-test screen

Admit new patient or select patient from list

Apply electrodes and check signal quality

Enter the test information

Select protocol

Click button and wait for ST values to be displayed (option)

Start pedalling

Maintains the load stage

Switches to the next load stage (only with ERGOLINE 900/900L)

Modifies the load in 5-Watt increments

Selects the recovery phase

Quits program

MEDITRONIC M 700, ERGOCOMP EC 1200

Start program

Call up the exercise-test screen

Admit new patient or select patient from list

Apply electrodes and check signal quality

Enter the test information

Select protocol

Click button and wait for ST values to be displayed (option)

Start pedalling

Load changes can be made at the ergometer only (with M700 only for the custom-programmed protocols)

Selects the recovery phase

Quits program

Treadmill

Start program

Activate exercise-test mode

Enter new patient data or select patient from list

Apply electrodes and check signal quality

Enter the test information

Select test protocol

Record resting ECG (supine patient)

Record resting ECG (standing patient)

Record ECG of hyperventilating patient

Starts pre-test phase

Starts exercise test

Advance to the next load stage

Maintains the stage

Modifies the speed and grade (note: interrupts automatic program control)

Stops treadmill (without interrupting the test)

Restarts treadmill

Selects the recovery phase

Quits program

For your notes

4.3 The STAT ECG

The STAT ECG function allows you to record a resting ECG and save an ECG of up to 30 minutes duration. The first 10 seconds of the recording will be analyzed and you will obtain the same report (on screen and via the printer) as for the resting ECG.

This section describes the operating steps necessary to record a STAT ECG, namely how to

– apply the electrodes to the patient and connect the patient

– record the ECG

– call up the report pages for on-screen review

– select the default system settings

– Printing the report and comparing two ECGs is described in sections 4.1.5, 4.1.6 and 4.1.7 (this is identical with the resting ECG). In these sections you will also be informed on how to display the stored full-disclosure ECG.

The brief operating instructions at the end of this section sum up what you have to do to record a STAT ECG.

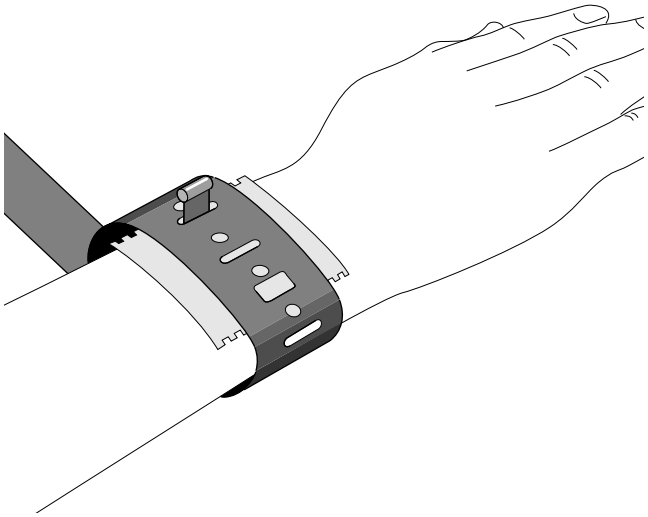


Figure 4.3-1. Applying plate electrodes

4.3.1 Applying the Electrodes

Careful application of the electrodes is a prerequisite for obtaining interference-free ECGs. The signal acquisition screen immediately gives you a visual indication of your electrode technique and of the signal quality (provided the red R electrode is applied).

For quick, reliable and trouble-free application of the electrodes we recommend our Electrode Application System (refer to the Electrode Application System operator's manual).

As an alternative you can use the conventional plate electrodes on the limbs and the suction electrodes on the thorax.

Applying Plate Electrodes (Limbs)

Plate electrodes are applied by means of a rubber strap; electrode paper is the recommended contact medium for this type of electrode.

* Moisten the electrode paper with tap water and place it between skin and electrode.

* Secure the electrode with the rubber strap (Figure 4.3-1) so that it cannot shift during the recording; take care not to strangulate blood vessels in the process.

☞ ***The red R electrode is the reference electrode. Placement and signal quality of all other electrodes can be assessed on the signal acquisition screen only when this electrode is applied.***

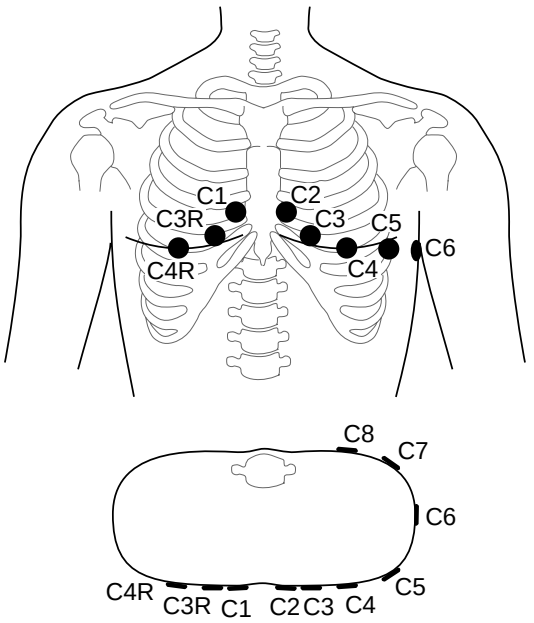


Figure 4.3-2. Chest electrode application points

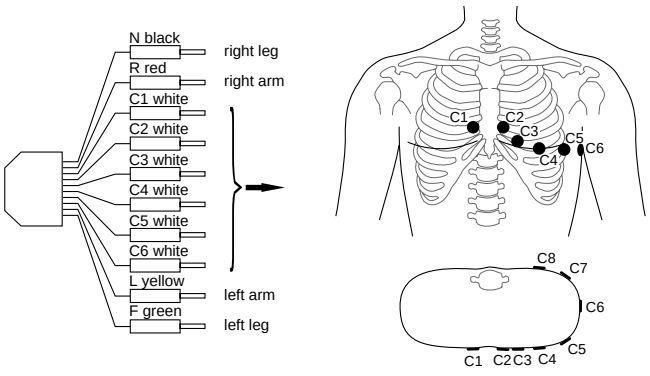


Figure 4.3-3. Connecting the patient cable (10-wire, standard ECG leads)

Applying Suction Electrodes (Thorax)

* Shave application points, if necessary.

* Moisten electrode paper with tap water and place it between skin and electrode. Electrode cream or gel can be used here instead of the paper. Especially when the chest is a little hairy, cream or gel helps to seal.

Electrode Application Points for Standard Leads (I, II, III, aVR, aVL, aVF, V1 to V6)

Four limb and six chest electrodes must be applied for acquisition of the standard leads. Attach the limb electrodes above the wrists and ankles. Figure 4.3-2 shows the chest lead application points:

C1 in the 4th intercostal space at the right sternal edge
C2 in the 4th intercostal space at the left sternal edge
C3 at the level of the 5th rib midway between C2 and C4
C4 in the 5th intercostal space on the left midclavicular line
C5 on the left anterior axillary line between C4 and C6
C6 on the mid-axillary line at the level of C4
C7 in the 5th intercostal space on the left posterior axillary line
C8 in the 5th intercostal space on the left scapulary line
C3R opposite C3, on the right side of the thorax
C4R opposite C4, on the right side of the thorax

* Connect the 10-wire patient cable as shown in Figure 4.3-3.

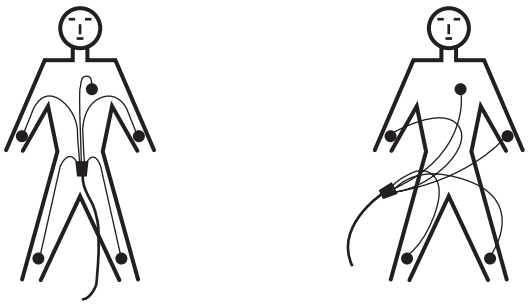


Figure 4.3-4. Arranging the patient cable

* Arrange the patient cable as shown in Figure 4.3-4 and connect it to the system (type CF signal input: highly isolated, suitable for intracardiac application, defibrillation-proof).

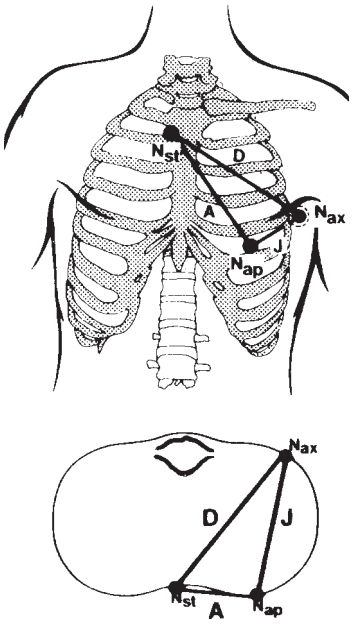


Figure 4.3-5. Electrode application points for NEHB leads

- N_{st} *attachment point of the 2nd rib to the right sternal edge*
- N_{ax} *in the 5th intercostal space on the left posterior axillary line (identical with C8)*
- N_{ap} *in the 5th intercostal space on the left mid-clavicular line (identical with C4)*

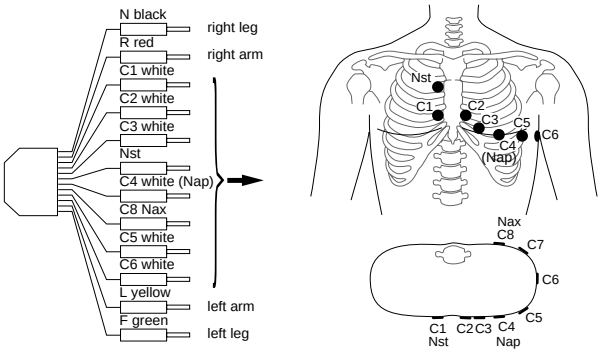


Figure 4.3-6. Connecting the patient cable (12-wire, NEHB leads)

Electrode Application Points for NEHB Leads

Figure 4.3-5 shows the application points for the NEHB electrodes. Connect the 12-wire patient cable as shown in Figure 4.3-6 (N_{ap} is identical with C4).

* If necessary disable the anti-drift system and the filters (muscle and AC line filter) to view the unfiltered "raw" ECG signal (sections 4.3.2 and 4.3.4).

As an alternative the NEHB leads can also be acquired with the 10-wire patient cable. In this case, select the sequence High, Right or Left as described in section 4.1.7 ("Modifying the Lead Sequence") and change:

I	to	D
II	to	A
III	to	J.

Apply the R electrode to Nst
the L electrode to Nax (C8)
the F electrode to Nap (C4).

☞ ***It is not possible to record chest leads at the same time as NEHB leads.***

☞ ***Please observe the information given in sections 7.1 ""Artifact Due to Poor Electrode Application", 7.2 "ECGs of Pacemaker Patients" and 7.3 "ECG Recording During Defibrillation" in the appendix.***

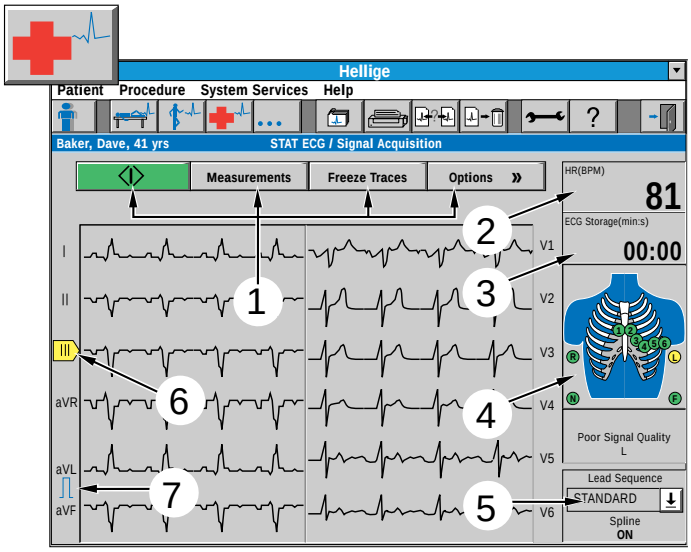


Figure 4.3-7. Signal acquisition screen for the STAT ECG

1 *Control buttons*
2 *Current heart rate*
3 *Remaining full-disclosure ECG storage time*
4 *Applied electrodes*
green: properly applied
yellow: not properly applied
white: site not used
red: electrode off or lead break
5 *For selection of the lead sequence*
6 *Leads impaired by poor signal quality*
7 *Calibration pulse*

> ***The applied electrodes are shown on the torso only for the "Standard" and "CABRERA" lead sequences. In all other cases there is only a schematic representation of the electrodes. The reference electrode R (red) must be applied for the lead-check function to work properly.***

4.3.2 The STAT ECG Acquisition Screen

Click on to display the STAT ECG signal acquisition screen.

The signal acquisition screen (Figure 4.3-7) shows:

– the current heart rate (2) and the remaining storage time for the full-disclosure ECG (3)

– the applied electrodes and the signal quality (4). Furthermore an arrow (6) points to the leads which are impaired by improper electrode application or which cannot be recorded due to disconnected electrodes (or due to a break in the patient cable).

– the selected lead sequence (5) (click on to select another lead sequence)

– the selected gain (the 1-mV calibration pulse (7) is valid for all channels).

This program allows you to select specific system settings similar to a conventional ECG recorder. You can enable or disable muscle and AC line filters, select different sweep speeds and sensitivities, etc. Furthermore, you can set up the system to suit your personal needs and preferences. These settings will be retained and are activated each time the system is turned on (section 4.3.4 "Setup"). From the setup menu you also choose the format for the in-test reports.

☞ ***The system can be set up to display the patient selection screen when the STAT ECG is activated.***

☞ ***Please remember that a filter may also suppress diagnostically relevant information, as it limits the frequency bandwidth. Therefore you should not switch filters on indiscriminately.***

☞ ***Settings selected from the setup menu will be retained and are automatically activated each time the system is turned on.***

☞ ***The test information screen appears automatically when you check the "Patient Selection Prior to STAT ECG" box in the system setup menu. The same screen can also be displayed by clicking on the*** Test Information ***button.***

Click Options >> to display the system settings buttons.

Select Setup to display the setup menu (section 4.3.4).

The 40 Hz box switches a muscle filter on and off

The 50 Hz check box switches an AC filter on and off (☒ = AC filter on).

The arrows at ... mm/mV select the gain (2.5, 5, 10, 20, 40 mm/mV).

The arrows at ... mm/s select the trace sweep speed (25 or 50 mm/s).

The entire ECG recording is controlled with the four buttons:

The following pages explain the operating steps required to record a STAT ECG.

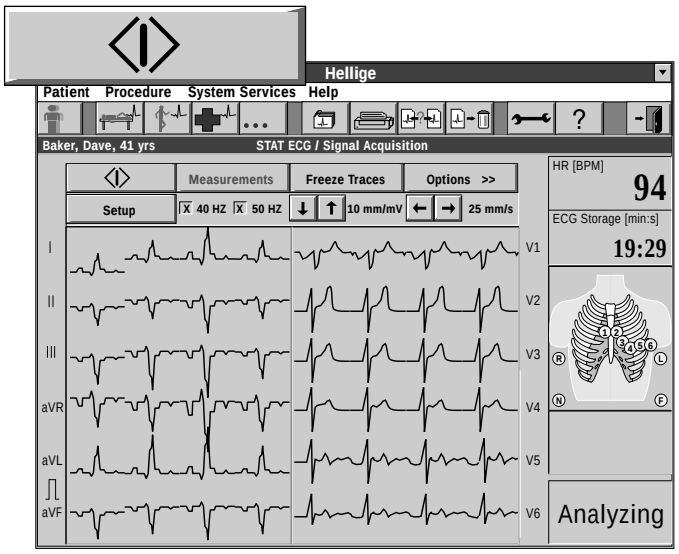


Figure 4.3-8. STAT ECG acquisition screen

> ***The system may be configured to display the patient selection screen before the signal acquisition screen.***

> ***At the end of the analysis the*** [Setup] ***button turns into the*** [Event Mark] ***button and the*** [Start Rhythm] ***button appears instead of the filter check boxes.***

4.3.3 Recording a STAT ECG

When you click [⟨I⟩], the program starts analyzing the first 10 seconds of the ECG. The analysis results are displayed in the lower portion of the screen. Then the program continues collecting the ECG, at the same time scanning it for arrhythmias such as fibrillation/flutter, ventricular tachycardia, either until the set time has elapsed or until you click [▽].

Click the [⟨I⟩] button: The signal acquisition screen appears (Figure 4.3-8).

In the bottom right-hand corner the system informs you of its current activities. Below the heart rate you see the time remaining for ECG storage. At the end of the analysis the results are automatically displayed.

Click [Freeze Traces] to freeze and release the ECG trace (except channel 1).

Click [Measurements] to display or suppress the results of the ECG analyis.

Click [▽] to terminate full-disclosure ECG acquisition (when the set time has elapsed, the program stops automatically collecting the ECG).

Click [Options >>] to display or suppress the second line of control buttons.

Click [Event Mark] to display a marker.

The Start Rhythm button initiates the thermal writer. It will record the ECG displayed on the monitor screen until stopped with the Stop Rhythm button.

At the end of the session the program asks you whether or not you wish to save the results (select a patient).

You obtain the same report documents as those described in section 4.1.4 “Recording a Resting ECG”) as well as the full-disclosure ECG as described in section 4.2.4 “Running and Assessing an Exercise Test” (Figures 4.2-39 and 4.2-40).

However, in the STAT ECG mode it is not possible to save episodes.

It is possible to compare two or more STAT ECG recordings (section 4.1.5 “Comparing Two ECGs”).

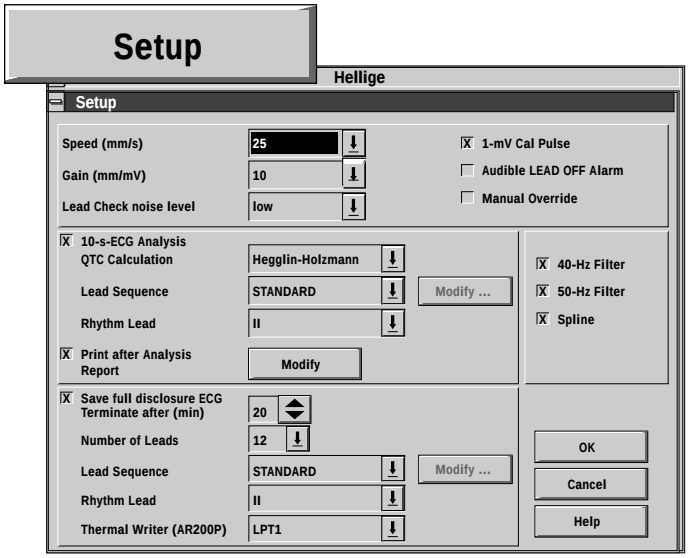


Figure 4.3-9. The setup menu

4.3.4 Setup

Click Setup to call up the setup menu (Figure 4.3-9).

Use this screen to select your personal system settings.

Adjustments are made in three different ways:

1 There is an arrow at the end of a box ↓.
Clicking this arrow will open a window which offers various options. Select the desired setting by clicking the mouse button.

2 There is a check box in front of the function. Click the box to enable or disable the function (☒ function enabled).

3 Click the Modify... button (for instance, to select the Lead sequence).

Top Window

Speed
selects the trace sweep speed.

Gain
selects the signal size (amplitude)

Lead Check noise level
This is a measure of the quality of the acquired signal (signal to noise ratio). When there is too much signal noise at the electrode, the electrode is displayed yellow on the signal acquisition screen. The setting that you select here (low, middle, high) changes the threshold as of which the electrode is displayed yellow (high sensitivity to noise = low threshold).

1-mV Cal Signal
display of 1-mV calibration pulse: yes or no (☒ yes)

Audible LEAD OFF Alarm
audible signal when an electrode is disconnected: yes or no (☒ yes)

Manual Override
When the function is enabled, the program will start the signal acquisition, even if not all electrodes are applied.

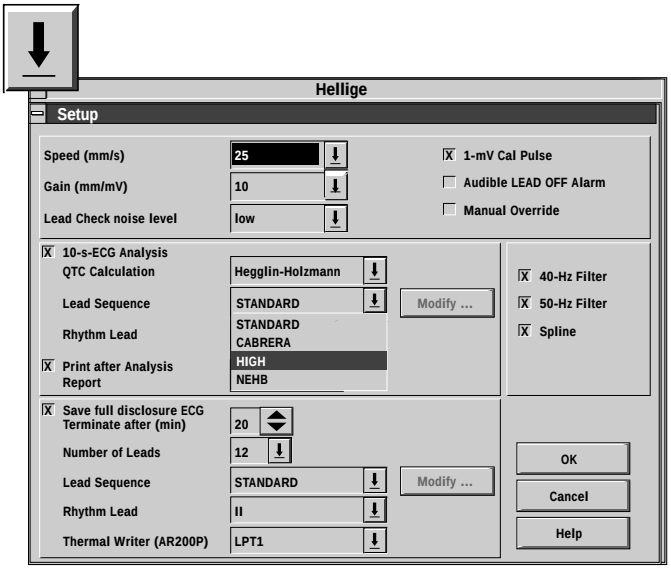


Figure 4.3-10. Lead sequence selection window

Middle Window

10-s ECG Analysis

Here you determine wheter or not an ECG analysis is to be made prior to the recording (yes, no). An analysis is possible only when all 10 electrodes are applied. All adjustments made in this field only refer to the 10-s ECG analysis (e. g. lead sequence).

QTC Calculation

Equation for calculation of the QT interval: HEGGLIN-HOLZMANN or BAZETT.

Lead Sequence

In the lead sequence window you can assign the leads to the recording channels. Six lead sequences are predefined. Four of these (sequences 3 to 6) can be modified.

STANDARD:	I, II, III, aVR, aVL, aVF, V1...V6
CABRERA:	aVL, I, -aVR, II, aVF, III, V1...V6
HIGH:	I, II, III, aVR, aVL, aVF, V1'...V6'
NEHB:	I, II, III, aVR, aVL, aVF, D, A, J, D, A, J
LEFT:	I, II, III, aVR, aVL, aVF, V4, V5, V6, V7, V8, V9
RIGHT:	I, II, III, aVR, aVL, aVF, V4R, V3R, V4, V1, V2, V3

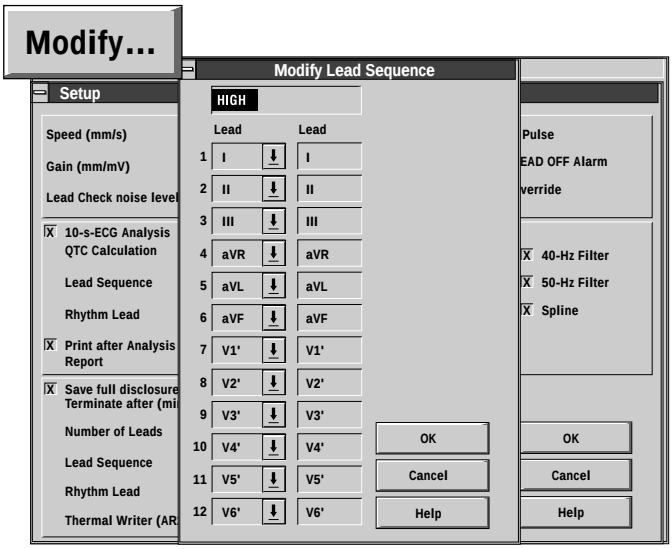


Figure 4.3-11. Modifying the lead sequence

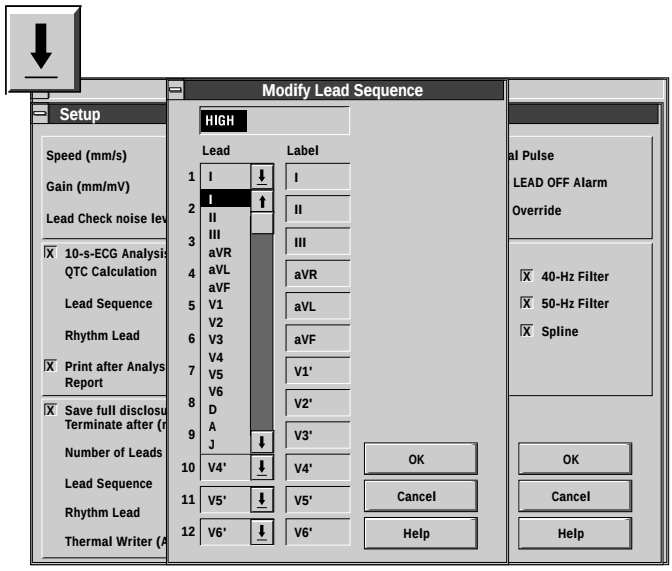


Figure 4.3-12. Modifying the lead sequence

Modifying the Lead Sequence

Click the ↓ box to the right of Lead Sequence to open the Lead Sequence selection window (Figure 4.3-10).

Click the sequence that you wish to modify (lead sequences 3 to 6 only).

Click Modify... to open a window showing all channels (Figure 4.3-11). There is a window for each of the channels indicating the lead currently assigned to that channel. To select another lead

Click the arrow ↓ to display all available leads (Figure 4.3-12).

Select the new lead to be recorded in the respective channel.

Enter up to 4 characters in the “Label” column to label the lead.

Once you have assigned a lead to each of the channels, you can enter a name for the lead sequence in the headline.

Move the cursor to the text box and click.

Enter a name and select OK to clear the window.

Rhythm Lead
Selection of the rhythm or reference lead.

Print after Recording
After analysis of the 10-s ECG, a report is printed automatically, yes/no. The scope of the printout is determined with menu item “Report Modify”.

40-Hz Filter
enables or disables muscle filter (☒ muscle filter on)

50-Hz/60-Hz Filter
enables or disables AC filter (☒ AC filter on)

Spline
enables or disables the Cubic Spline algorithm (automatic baseline correction, ☒ Spline on); the algorithm causes a signal delay of 4 seconds.

Bottom Window

Save full disclosure ECG / Terminate after [min]
You can choose a time interval after which the program automatically stops collecting the ECG signal (30 min max.).

Number of Leads
Selection of the number of leads to be stored (6 or 12).

Lead Sequence
Here you determine the lead sequence for the ECG saved online.

Rhythm Lead
Selection of the rhythm or reference lead (Save FD ECG).

Thermal Writer
Selection of the thermal printer port (for printout of the online ECG, refer to section 4.3.4 “Recording a STAT ECG”). Select “none”, when no printer is connected.

Audible LEAD OFF Alarm
Audio signal when an electrode is disconnected, yes/no.

10-s ECG Analysis
ECG analysis at the beginning of the recording (☒ yes, ☐ no). Possible only when all 10 electrodes are connected.

Report Modify
Here you determine the scope of the printed report. The special configuration screen is described in detail in section 4.1.6 “Printing the Resting ECG”.

Print after Analysis
Do you wish to print the report configured on the screen mentioned above after each STAT ECG recording or not?

4.3.5 Recording a STAT ECG (Brief Operating Instructions)

Turn on system and activate the STAT ECG program

Apply electrodes and check signal quality

Select procedure parameters (sweep speed, gain, lead sequence)

Enter the test information

Watch ECG traces and – when the most recent 10 seconds are without artifacts – start recording (the first 6 s are analyzed, then the system starts signal acquisition)

The recording ends automatically when the selected time has elapsed or when you press the button

The 10-s ECG segments are displayed

Scroll through the report or

access documents directly

Proceed to next procedure or

Quit program

4.4 The Spirometry Test

A spirometry test includes

– measurement of the expiratory and inspiratory vital capacity (VC) plus presentation of the expiratory volume-time curve

– measurement of the expiratory and inspiratory forced vital capacity (FVC) plus presentation of the volume-time and flow-volume curves

A parameter table lists all measured values, the normal values and the percentage deviation of each parameter.

You can also run two procedures as a so-called broncho-dilation test. For this purpose two tests (one before and one after medication) are compared.

This section tells you how to

– connect the respiration flow sensor

– enter the test information and patient data (reason for test, medication, comments, etc.)

– conduct a test

– call up and print the report pages

– compare two tests

– set up the system to suit your needs (setup menu)

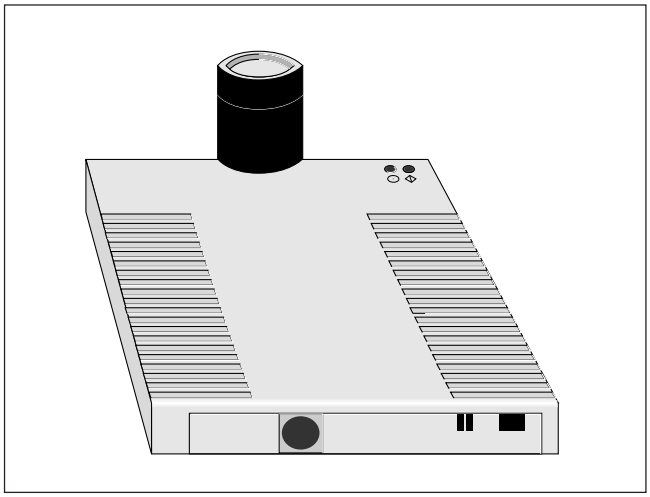


Figure 4.4-1. Respiration Flow Sensor LF 501

4.4.1 Connecting the Respiration Flow Sensor LF 501

The respiration flow sensor is connected to the interface selected from the setup menu (section 4.4.7 “Setting up the Spirometry System”). The factory-set interface is COM2.

For detailed user instructions and specifications, please refer to the LF 501 operator’s manual 227 362 02.

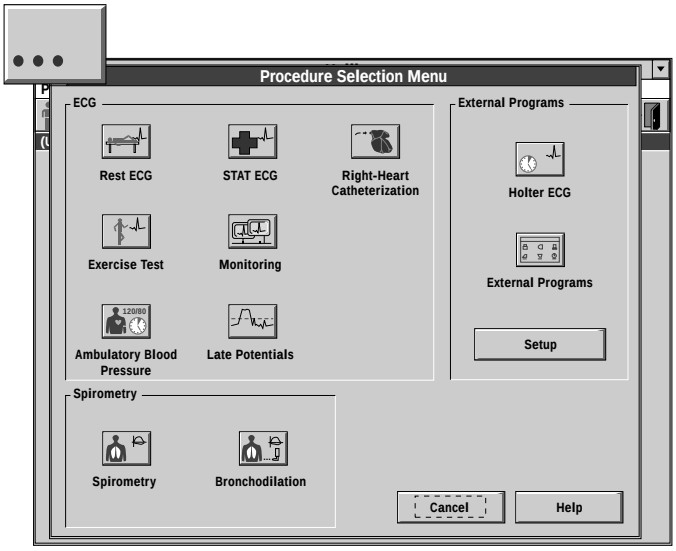


Figure 4.4-2. Procedure Selection screen

4.4.2 The Basics

Click to display the spirometry procedure screen. You will find this icon on the procedure selection screen, unless you have configured the icon bar to include that symbol (section 6. “System Services”).

Click to display the procedure selection screen (Figure 4.4-2).

Click to display the spirometry procedure screen.

Once you select a patient, the system will display the test information entry screen (Figure 4.4-3).

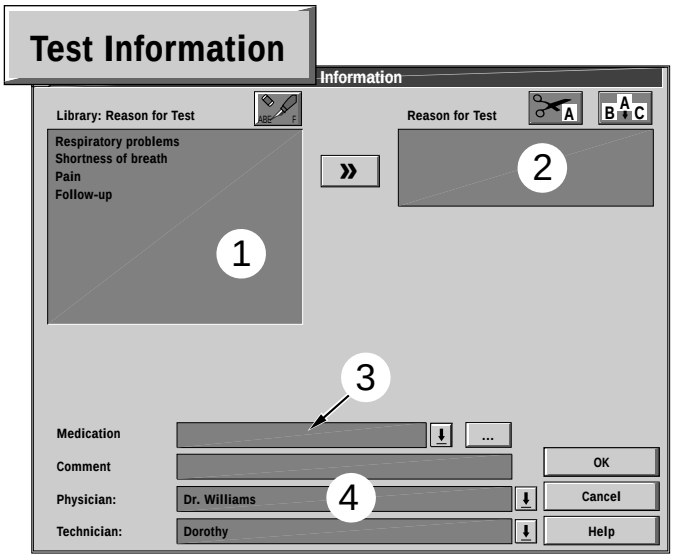


Figure 4.4-3. The test information entry screen

1 Standard reasons for test
2 The patient's reason for test
3 Medication
4 Boxes for entry of comments and of the physician's and technician's names

4.4.3 Entering the Test Information

The test information screen provides space for entry of important information pertaining to the spirometry test.

These are:
– the reasons for test
– the medication
– comments
– the technician's and the physician's names.

Copying Statements from the Library to the Patient Window

The system provides a library whose statements can be easily copied to the patient's window. You can add statements or edit existing ones as required.

Highlight a statement by clicking.

Click the » button.

If you wish to delete a copied statement or part of it, highlight the words in question and click A.

The deleted words can be inserted in another position by placing the cursor there and clicking A B C.

You can enter a statement directly by moving the cursor to the desired position and typing the text.

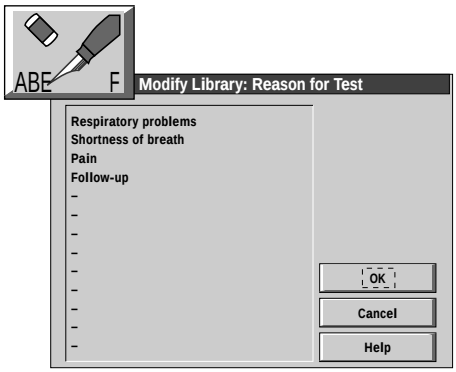


Figure 4.4-4. Editing the Reason for Test

> ☞ ***A statement is easily copied to the window at right by double-clicking!***

Editing the Library

Click .

This will open the library window (Figure 4.4-4).

Move the cursor to the desired position in the list and click the mouse button.

Enter the statement and press on the keyboard. The cursor moves to the beginning of the next line.

In this manner you may enter all reasons for test. Click OK to clear the window.

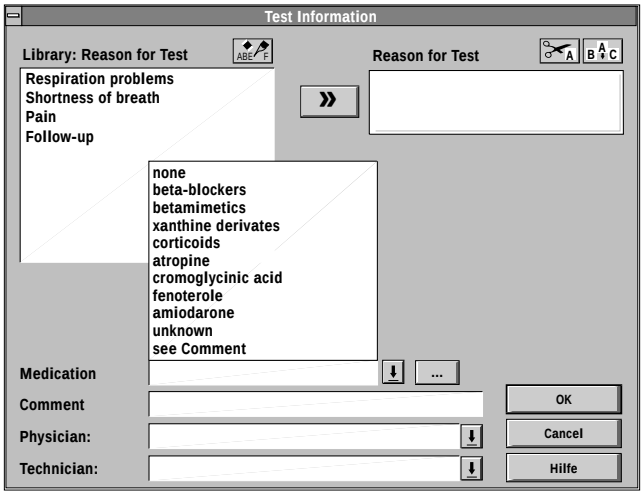


Figure 4.4-5. List of medication groups

1 Allows you to assign a drug to a medication group

> ***The physician is responsible for assigning drugs to a medication group.***

Figure 4.4-6. Assigning a drug to a medication group

Selecting a Medication, Assigning a Drug Name to a - Medication Group

You can select a medication from a list of 14 items ⬇. You can also assign specific drugs to the medication groups to include these in the list instead of the group name.

Making a Selection

- Click on ⬇ to open the medication list box (Figure 4.4-5).
- Select one of the medications.
- If you wish to select a second medication or to assign a drug name to a medication group, click on ... and select the medication as described above.

Assigning Drugs to a Medication Group

- Click on Medications....

A window opens, showing medication group names (Figure 4.4-6). There is a drug name window for each of these groups. Click on the respective text box, if you wish to enter a name. Then type the drug name.

Furthermore, you are free to arrange the medication groups any way you want. To do so

- Click on the ⬇ at the end of the group name box.

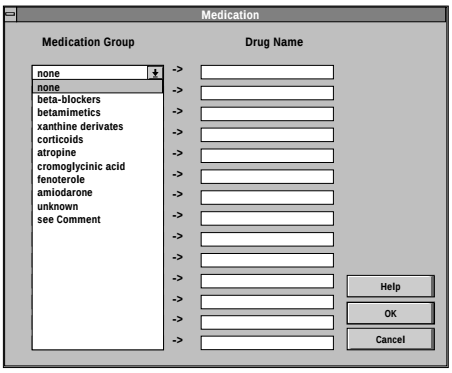


Figure 4.4-7. Editing the medication group

Simply press ↵ on the keyboard to save the data and clear the window.

This brings up a new window where you can choose one of the group names (Figure 4.4-7).

Click on the drug name box and enter the name

Click on OK to clear the window.

Entering Comments

If you wish to enter a comment on the test procedure, click in the “Comment” text box and key in the text.

Physician’s/Technician’s Name

The names of the physician and technician can either be entered here (click in the text box and type the name), or they can be selected from the list of the registered system users (section 6.1 “System Configuration”).

Click on ↓ and choose a name from the list by clicking on it.

Exiting the Test Information Screen

Once you have entered all test information, you can either

– clear the window with OK or

– clear the window with Cancel (in this case the information will be ignored and is not assigned to the test) to display the test control screen.

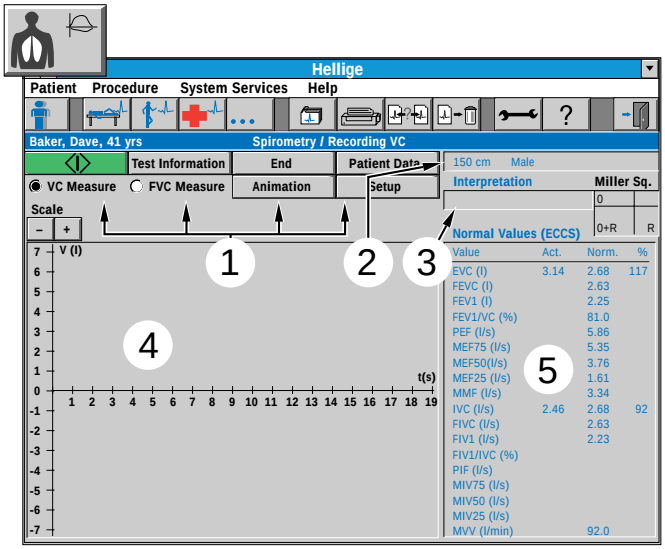


Figure 4.4-8. Spirometry procedure screen

1 Control buttons
2 Patient data
3 Field for interpretation, MILLER square
4 Respiration trace
5 Parameter table

4.4.4 Running and Evaluating a Spirometry Test

The Spirometry Test Screen

Once you enter the test information, the system will display the spirometry test screen (Figure 4.4-8).

On this screen you see

– the control buttons (1)

– the patient data (2)

– a field for interpretation and the MILLER square (3)

– a window for display of the recorded trace (4)

– a table listing the normal values, the actual values and the deviation as a percentage (5).

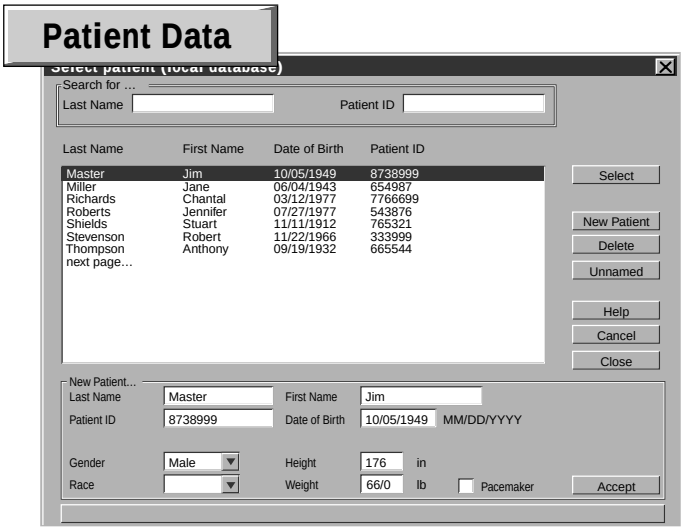


Figure 4.4-9. Patient data screen

Modifying Patient Data

For calculation of the spirometric normal values, the program needs the following patient data:

age
height
gender.

Without these data which are adopted from the patient file (section 3. “Selecting and Admitting a Patient”) the normal values cannot be derived. Height, age and gender are displayed on the spirometry procedure screen (Figure 4.4-8).

If you wish to verify or modify these data, click Patient Data to display the patient data screen (Figure 4.4-9).

Change height and/or weight by clicking the respective box, then enter the new value(s) via the keyboard.

Enter the patient’s gender by clicking the arrow and selecting the appropriate option.

Select OK to terminate entry or modification of the patient data.

Running a Spirometry Test

Before conducting the first test, specific system settings should be selected from the setup menu (section 4.4.7 “Spirometry System Setup”).

The test is conducted with the control buttons (1, Figure 4.4-8).

You can measure the vital capacity VC and the forced vital capacity FVC and combine both to form a bronchodilation test (section 4.4.5). Click to select the bronchodilation test, or to select a standard spirometry test.

If the first procedure of a bronchodilation test was run as a normal spirometry test, the program asks you before the second test, whether the first one is to be taken as the reference measurement.

☞ ***Before each test, attach a new mouthpiece with bacterial filter to the sensor.***

Before the test, we recommend that you give the patient an idea of the test by demonstrating the animation.

Click Animation to start the demonstration.

When the patient is familiar with the test procedure, you can start the test.

Attach the nose clip, so that the entire tidal volume flows through the sensor.

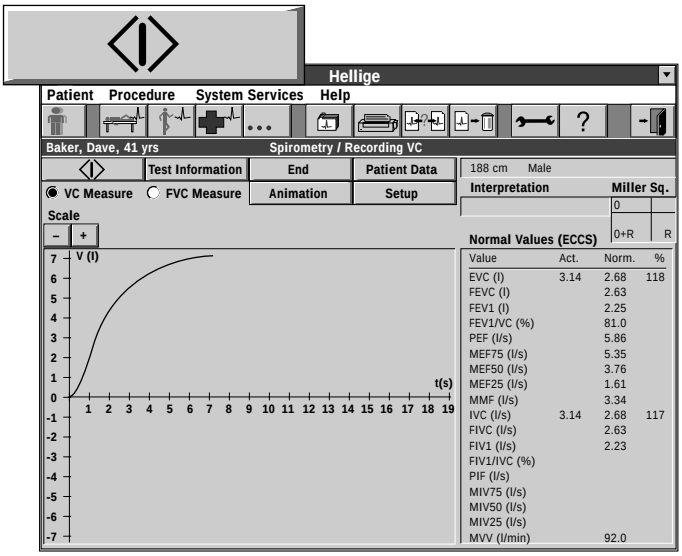


Figure 4.4-10. VC measurement

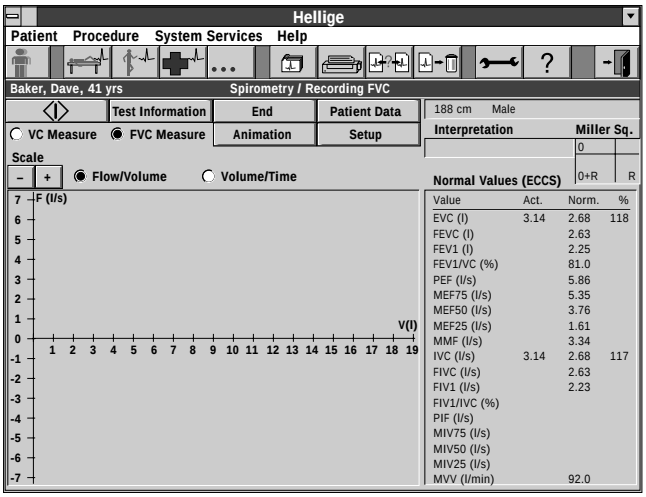


Figure 4.4-11. FVC screen

Click [◁▷] and ask your patient to inhale, exhale and inhale again as deeply as possible through the sensor, when the orange indicator on the sensor lights up. Then your patient may resume normal breathing.

The maneuver must be concluded within 20 s of clicking [◁▷]. The program terminates the measurement when it does not detect a flow reversal within 4 s of two identified inversion points, or after five full breaths.

The recording area shows the volume-time curve (expiration only) and the table lists the parameter readings and percentage deviations from the normal values.

Click [◁▷] to initiate further measurements. The next curve is depicted with another color and displayed on top of the first one. The best results for EVC and IVC, which are not necessarily taken from the same test, give VCmax.

Click Scale [- +] if you wish to change the curve size.

Select ○ **FVC Measure** to measure the forced vital capacity. You will see a screen similar to Figure 4.4.-11.

Demonstrate the FVC procedure as well ([Animation]).

Start the procedure, when the patient knows what to do.

Check the nose clip is in place.

Click ◁▷ and ask the patient to inhale deeply through the sensor when the orange indicator at the sensor lights up. Then the patient should exhale as quickly and completely as possible and inhale again as deeply as possible. Afterwards your patient may resume normal breathing.

This maneuver too must be concluded within 20 s of clicking ◁▷. The program terminates the measurement when it does not detect a flow reversal within 4 s of two identified inversion points, or after five full breaths.

The recording area shows the flow-volume curve and the table lists the parameter readings and percentage deviations from the normal values. The program also presents an interpretation (obstruction/restriction) and marks the results in the Miller square (Figure 4.4-11).

Click ◁▷ to initiate further measurements. The next curve is depicted with another color and displayed on top of the first one. The best results for FEVC are used. The interpretation, the mark in the Miller square and the results in the parameter table are always those of the most recent measurement.

The best result is the measurement giving the highest sum of FEVC + FEV1.

Click Scale - + if you wish to change the curve size.

Select ○ **Volume/Time** to return to the volume-time curve of the FVC measurement.

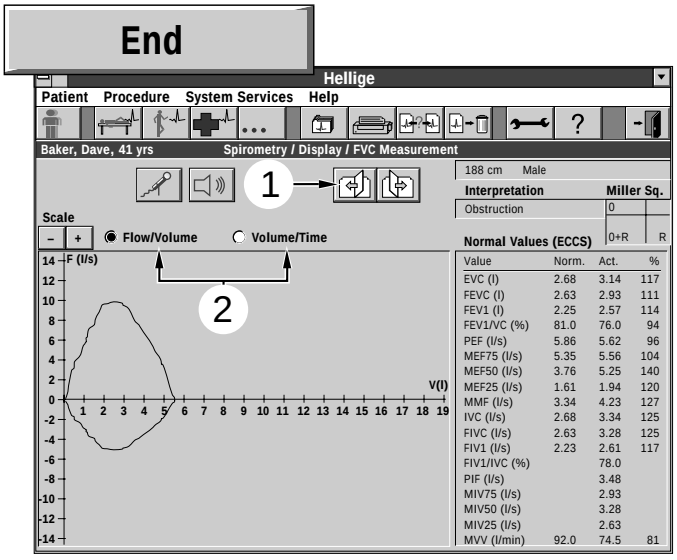


Figure 4.4-12. Report page

1 Button to call up the test information

2 Button to display the volume/time or the flow/volume curve

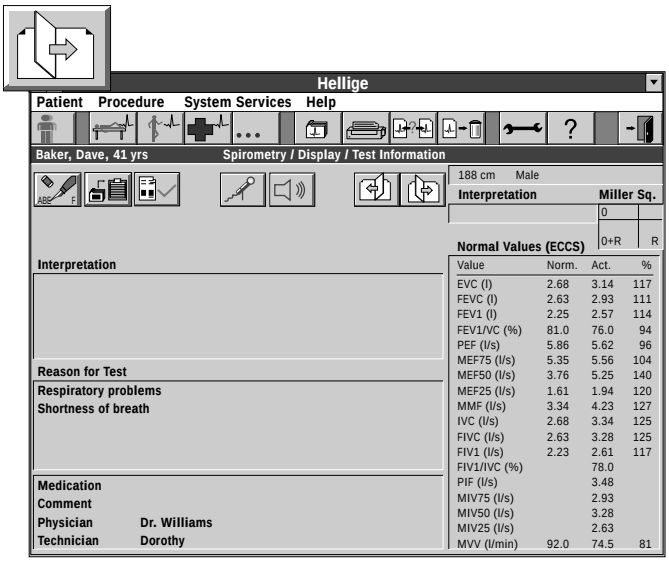


Figure 4.4-13. Test information

Click End to terminate this part of the test and display the report (Figure 4.4-12).

Click to display the test information screen (Figure 4.4-13).

The test information screen shows:

- the reason for test
- the interpretation made by the program
- the patient data
- medication, comments, physician, technician.

You can enter your own interpretation in the “Interpretation” window by placing the cursor in the window and typing the text.

You can record a spoken comment (button) and play it back later (button). For this feature you need a microphone, and a sound card must be implemented in your PC.

If you wish to enter or edit the test information, click on to display the corresponding dialog window.

Data Export

The icon allows you to export the most important data pertaining to the spirometry test to the clipboard or to any file. Data exported to the clipboard, for instance, can be inserted in a text file with the “Edit” —> “Paste” command.

Click .

Select either “Export data to clipboard” or “Export data to file”.

Click on OK.

Data from the clipboard can be inserted in a text file.

For data exported to a file you will have to specify the target directory and confirm it with OK.

Confirming Tests

A test is considered confirmed, when a physician has reviewed the test evaluation and “signed” it electronically with his/her name. Tests that have been reviewed and confirmed by a physician are marked with x.

Click on (Figure 4.4-13) to display the window where you can enter your name.

Select the physician’s name from the list box (click on) or enter it via the keyboard.

4.4.5 The Bronchodilation Test

The bronchodilation test always consists of two measurements, one before and one after medication.

Click to select the bronchodilation procedure.

The screen for VC measurement **before** medication will be displayed.

Perform the measurement as described in section 4.4.4.

Measure FVC in the same manner.

Click End to terminate the measurement.

These tests are saved and annotated as measurement “before bronchodilation”.

Administer the medication and select the bronchodilation procedure again.

The screen for VC measurement **after** medication will be displayed.

Perform measurement of VC and FVC again.

Click End to terminate the measurement.

You will now see both examinations on one screen so that you can compare the effects of the medication (section 4.4.6 “Comparing Two Spirograms”).

If you decide to run a bronchodilation test on a patient whose spirogram was recorded earlier that day you will be asked whether the first spirogram is to be taken as the reference test.

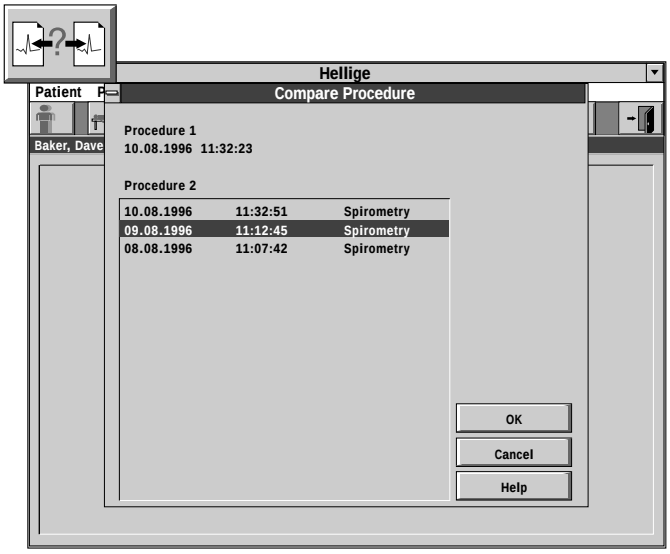


Figure 4.4-14. Spirometry selection window

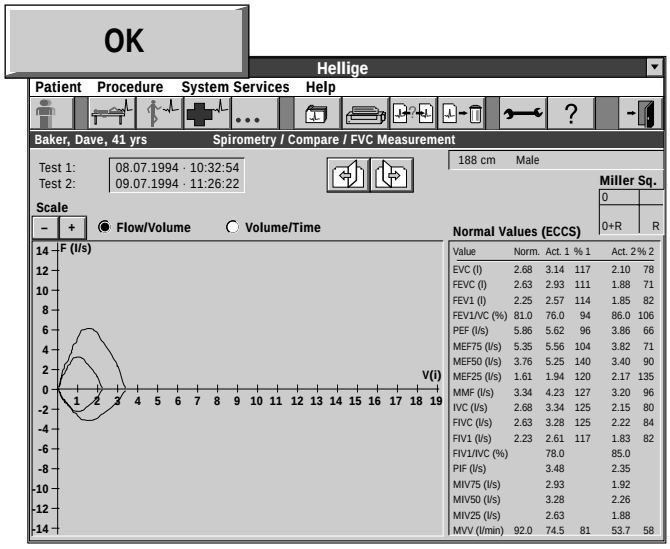


Figure 4.4-15. Comparing Two Spirograms

4.4.6 Comparing Two Spirograms

You can compare the present spirogram with another one recorded earlier. For the example below we assume that you wish to compare the recent spirogram with an earlier recording of the patient. Of course, you are free to call up any spirogram (section 3.3 “Editing Stored Tests”) and compare it with any other spirogram as described below:

Click .

A window will open listing all of the patient’s spirograms (Figure 4.4-14).

Select a spirogram.

Click . You will then see a report screen showing the respiration curves and parameter readings from both tests (Figure 4.4-15).

At the top of the screen you will see the most important results from both tests.

Click on and to display the other report pages.

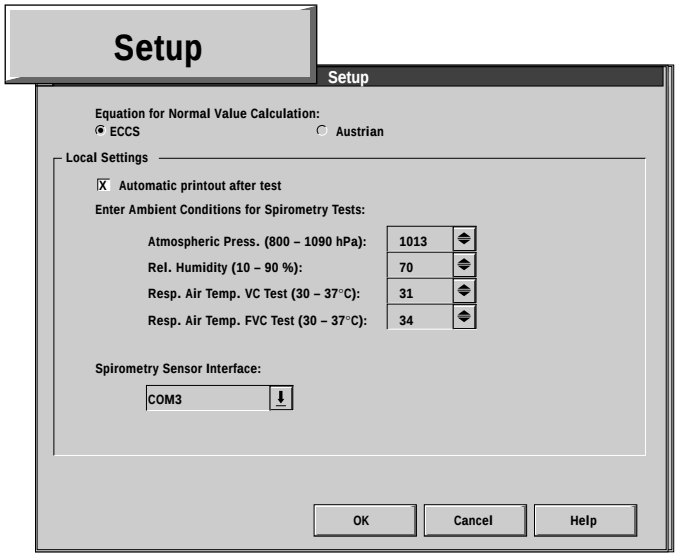


Figure 4.4-16. The setup screen

4.4.7 Spirometry System Setup

Before running the first spirometry test, you will have to select several system settings from the setup menu. These settings are saved and loaded automatically on power up.

Click [Setup] to display the defaults screen (Figure 4.4-16).

First you choose the equation to be used for calculation of the normal values for patients between 18 and 80 years of age: either ECCS (European Community Carbon & Steel) or the Austrian equation (for patients between 7 and 70 years of age). If the patients are older they are assumed to have the maximum age.

Having selected the ECCS equation, the normal values for patients between 7 and 17 years of age will be calculated according to QUANJER and TAMMELING. There are no normal values for patients < 7 years. Patients between 18 and 25 years of age are evaluated like patients of 25.

Select an equation by clicking the button.

Eventually check that the correct interface has been selected. To change the interface, click the arrow button [↓], then select the appropriate interface name.

Click [OK] to terminate the configuration session.

Check the ambient conditions. The program needs these values for the BTPS correction (Body Temperature Pressure Saturated, i.e., the values are referred to an ambient pressure and saturation with water vapor at a body temperature of 37 °C). For BTPS correction, click the arrow button to the right of the respective value (arrow up selects a higher value, arrow down selects a lower value). The respiration flow sensor measures the ambient temperature, so you don't have to enter this value manually.

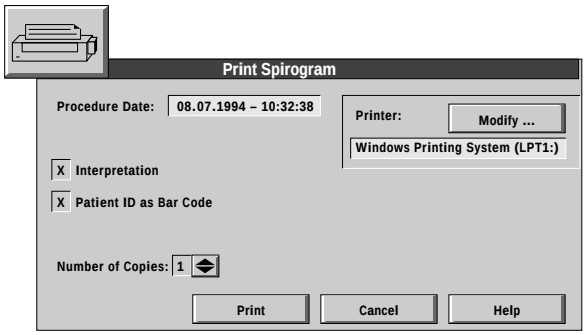


Figure 4.4-17. Print setup screen

4.4.8 Printing a Spirogram

Click to display the print setup screen (Figure 4.4-17).

Check that the correct procedure is selected.

Check the “Interpretation” box, if it is to be included in the printed report.

To select another printer, click **Modify...** in the printer window and select the new one with the mouse.

Click **Print** to initiate the printout, or click **Cancel** to quit the print screen.

4.4.9 Running a Spirometry Test (Brief Operating Instructions)

Turn on system

Display spirometry screen

Admit new patient or select patient from list

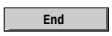
Enter test information

Attach nose clip

Initiate VC measurement and ask patient to breathe in, out and in again as deeply as possible through the mouthpiece

Repeat measurement or end this part of the test with

Initiate FVC measurement and ask patient to breathe in deeply through the mouthpiece. Then the patient is to breathe out and in again as deeply and quickly as possible

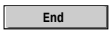
Repeat measurement or end the test with 

Display report

Bronchodilation Test

Display bronchodilation test screen

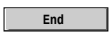
Perform VC and FVC measurements as described above



End measurement

Administer medication and display bronchodilation test screen again

Repeat VC and FVC measurements



End test

For your notes

4.5 Ambulatory Blood-Pressure Measurement

In this section you will learn how to perform ambulatory blood-pressure measurements, i.e.

– how to set up the recording unit

– how to configure the recording protocols

– how to download data from the recording unit to the PC and which report documents you may view

– how to print out the examination report

The brief operating instructions at the end of this section sum up what you have to do to perform ambulatory blood-pressure measurements.

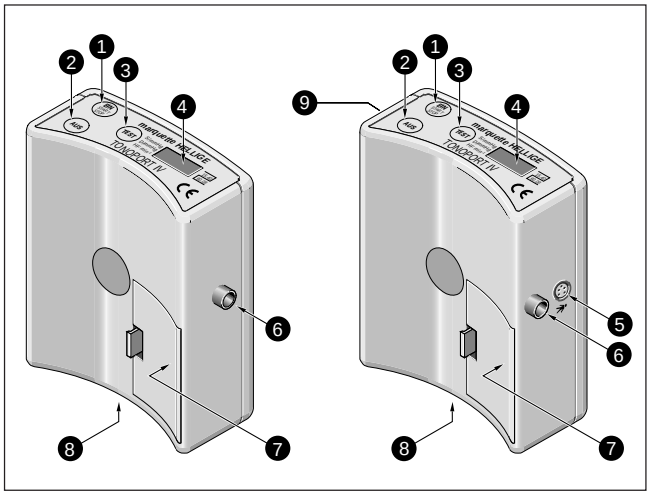


Figure 4.5-1. Displays, controls and connectors of the recording units (left: TONOPORT IV, right: TONOPORT IVa)

1 *ON button to turn on the recording unit. After the self test, this button is used to start and stop a measurement*
2 *OFF button to turn off the recording unit*
3 *TEST button to recall the most recently measured values. The values will be displayed in the following order:*
   – *systolic*
   – *diastolic*
   – *mean pressure*
   – *pulse rate*

   This button is also used to program the recording unit, when it is set up without a PC
4 *Liquid-crystal display*
5 *Patient cable connection (microphone, ECG)*
6 *Cuff connection*
7 *Battery compartment cover*
8 *Port for connection of PC, printer or power supply unit*
9 *Microphone sensitivity switch (TONOPORT IVa)*

4.5.1 General Information

The recording unit employed for ambulatory blood-pressure measurement is the TONOPORT IV/IVa unit. While the TONOPORT IV units only use the oscillometric measuring method, TONOPORT IVa units also offer the auscultatory method. Moreover, TONOPORT IVa units store the heart rate and ECG strips.

For information on how to set up and operate the recording unit, please refer to the TONOPORT IV/VIa operator's manual.

☞ ***Disconnect TONOPORT from the patient when it is connected to the PC!***

☞ ***When you see the message "Inconsistent data in patient monitor! Procedure cannot be saved!", turn off the patient monitor before downloading data.***

Caution

Switch off the patient monitor before connecting it to the PC. Furthermore, it is recommended to delete old data before starting a new ambulatory blood-pressure measurement.

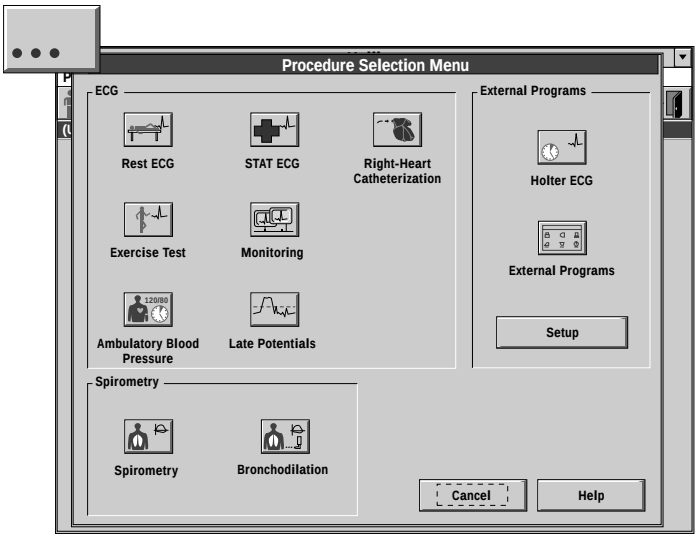


Figure 4.5-2. Procedure selection menu

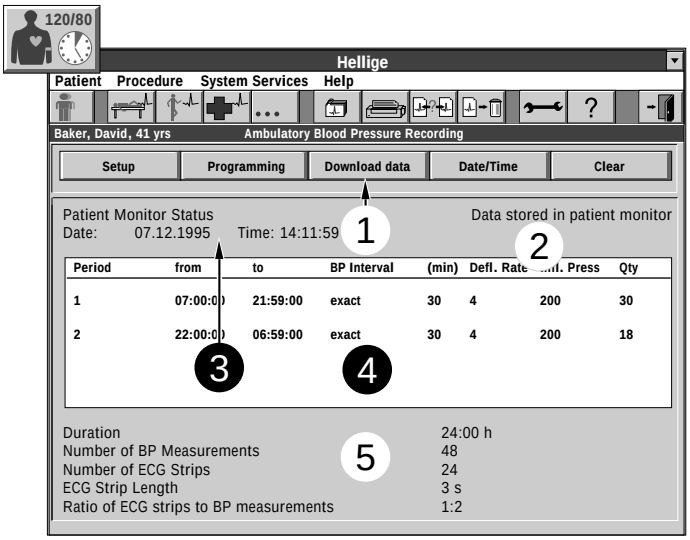


Figure 4.5-3. Ambulatory blood-pressure measurement, signal acquisition screen

1 Control buttons
2 Message indicating the memory status
3 Date and time of downloading from the recording unit
4 Memory status details
5 Summary of the stored data

4.5.2 Setting Up the Recording Unit

The Signal Acquisition Screen

Connect PC and recording unit with the cable provided, and turn on the recording unit. Before using the recording unit for the first time, you should specify the PC interface to which it is connected. This can be done via the signal acquisition screen.

The signal acquisition screen is displayed with the key. This key, in turn, is found on the procedure selection menu, unless you have configured the icon bar to include this icon (section 6 “System Configuration”).

Click on to display the procedure selection menu (Figure 4.5-2).

Click on to display the signal acquisition screen for ambulatory blood-pressure measurements.

Once the you have selected the patient, the signal acquisition screen (Figure 4.5-3) will be displayed.

On the signal acquisition screen you will see

– the control buttons (1)

– information on whether or not the recording unit contains data (2)

– a separate field for details of the memory status (3)

– a summary of the memory status (4)

The memory status field indicates the configuration of the recording unit.

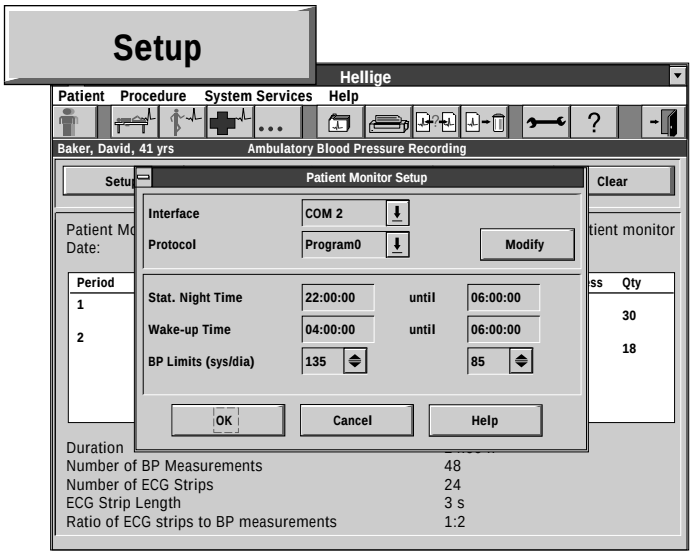


Figure 4.5-4. Window for entry of the interface and for protocol selection

> ***The recording unit can be programmed only when it contains no data.***

Specifying the Interface

Click on **Setup**.

Figure 4.5-4 will appear.

Click on ↓ to open the interface list box.

Select the interface.

Click on **OK** or **Cancel** to clear the window.

Setting Up the Recording Unit

Before setting up the recording unit, click on **Clear** to delete all data stored in the memory (Figure 4.5-3).

You can choose between two protocols to set up the recording unit. The protocol is selected with a mouse click. Both protocols can be edited to suit your patient's symptoms.

Click on **Setup**.

Figure 4.5-4 will appear.

Open the protocol selection window by clicking on ↓.

Select one of the protocols.

Enter the blood-pressure limits (▲ to increase the value, ▼ to decrease the value). After evaluation of the procedure data, the percentage of measurements which exceeded these limits is shown on the statistics summary page.

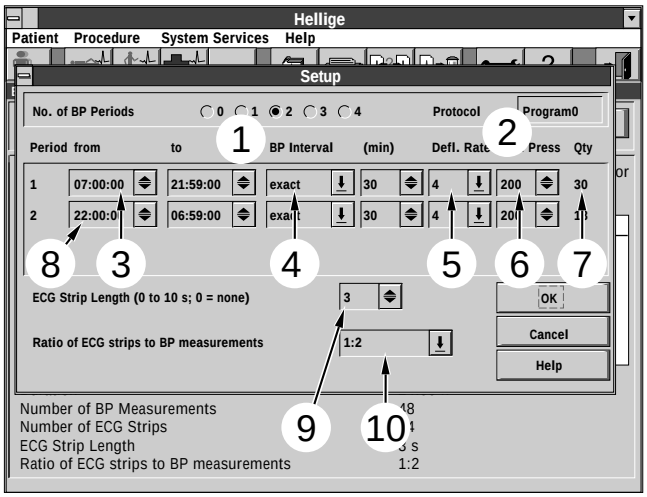


Figure 4.5-5. Protocol configuration menu

1 *Number of BP periods*
2 *Protocol name*
3 *Beginning and end of period 1*
4 *BP interval, period 1*
5 *Deflation rate, period 1*
6 *Cuff inflation pressure for initial measurement, period 1*
7 *Number of measurements taken during period 1*
8 *Details of period 2*
9 *ECG strip length (for TONOPORT IVa only)*
10 *Ratio of BP measurements to ECG recordings (for TONOPORT IVa only)*

In order to view the setup of the recording unit for a specific protocol, click on [Modify...]. You will then see the setup window (Figure 4.5-5) showing all the relevant data (see "Configuring Protocols" below). Click on [OK] to clear the window.

Click on [OK] or [Cancel] to clear the window.

Click on [Date/Time] to verify the date and the time.

To correct the displayed values, highlight the numbers and enter the correct value.

Click on [Programming].

If the date and the time of the recording unit differ from those of the PC, they can be corrected via the [Date/Time] function.

This completes the setup of the recording unit.

Turn off the recording unit and disconnect it from the PC.

Connect it to the patient (please refer to the TONOPORT IV/IVa operator's manual).

Turn on the recording unit and initiate the first measurement.

Configuring Protocols

The two protocols can be configured to suit the clinical picture of the patient to be monitored. The recording unit retains these modifications even when switched off.

- Display the setup screen as described above (Figure 4.5-5).

- First of all, select the number of blood-pressure periods for the protocol.

The day can be subdivided into up to 4 different periods, and different measuring intervals can be selected for each of these periods. Furthermore, you can choose whether the measurements are to be taken at “exactly” or at “approximately” the selected intervals. Selecting the approximate intervals is advisable for apprehensive patients who may be stressed knowing when a measurement is being taken. The deflation rate and the cuff inflation pressure are also adjusted in this menu.

The deflation rate can be set to any value between 1 and 8 mmHg (between oscillations). The deflation rate is fixed for auscultatory measurements.

The inflation pressure is the maximal pressure for cuff inflation.

- If you wish to modify the intervals or pressures click on ▲ to increase the value or on ▼ to decrease the value.

- The BP interval (exact, approx.) and the deflation rate can be changed by clicking on the list box ▼. Then you can select the desired setting.

For TONOPORT IVa you can also specify the length of the ECG strips (0 to 10 s) and whether an ECG strip is to be recorded for every, every second or every third blood-pressure measurement.

> ***The storage capacity for ECG strips is limited: the longer the strips, the less strips can be stored (232 1-second strips or 23 10-second strips).***

- Select OK to clear the setup menu.

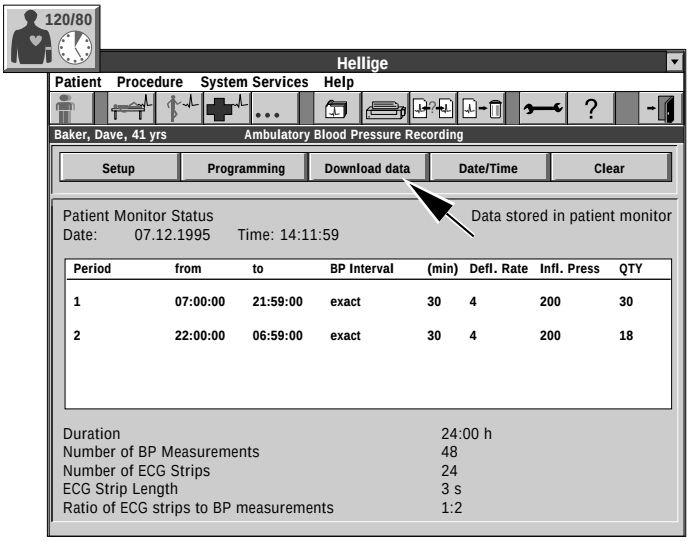

120/80
Hellige
Patient Procedure System Services Help
Baker, Dave, 41 yrs Ambulatory Blood Pressure Recording
Setup Programming Download data Date/Time Clear
Patient Monitor Status
Data stored in patient monitor
Date: 07.12.1995 Time: 14:11:59
Period from to BP Interval (min) Defl. Rate Infl. Press QTY
1 07:00:00 21:59:00 exact 30 4 200 30
2 22:00:00 06:59:00 exact 30 4 200 18
Duration 24:00 h
Number of BP Measurements 48
Number of ECG Strips 24
ECG Strip Length 3 s
Ratio of ECG strips to BP measurements 1:2

Figure 4.5-6. Signal acquisition screen, Download data button

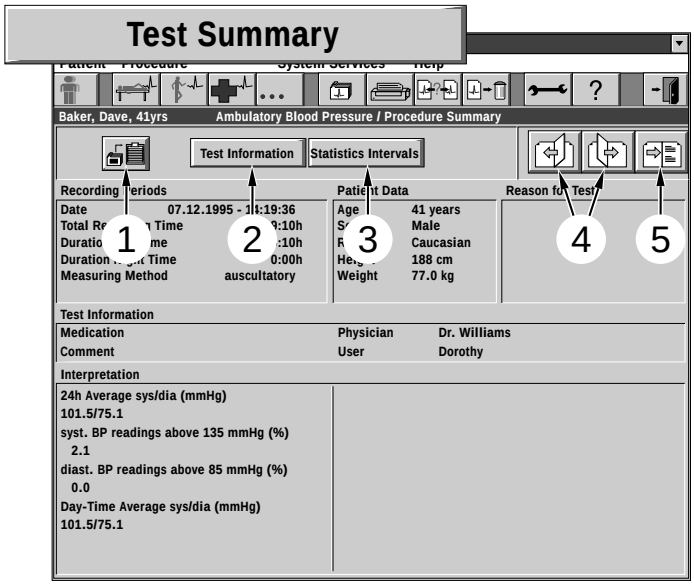


Figure 4.5-7. Test Summary

1 Button for data export

2 Button for entry of the test information

3 Button for entry of the statistics intervals

4 Buttons to display the other report documents (paging)

5 Button to directly access the other report documents

4.5.3 Data Output

Downloading data to the PC

The data stored in the recording unit must be downloaded to the PC for evaluation.

> ***Switch off the patient monitor before connecting it to the PC. Furthermore, it is recommended to delete old data before starting a new ambulatory blood-pressure measurement.***

Connect the recording unit to the PC and turn it on.

Display the signal acquisition screen for ambulatory blood-pressure measurements (Figure 4.5-6).

Click on Download data (Figure 4.5-6).

An icon indicates how the transfer proceeds. At the end you will be asked whether you wish to clear the data from the patient monitor. It is recommended always to delete old data so that the memory is free for collection of the new data. Then you will see the Test Summary (Figure 4.5-7).

> ***When you see the message "Inconsistent data in patient monitor! Procedure cannot be saved!", turn off the patient monitor before downloading data.***

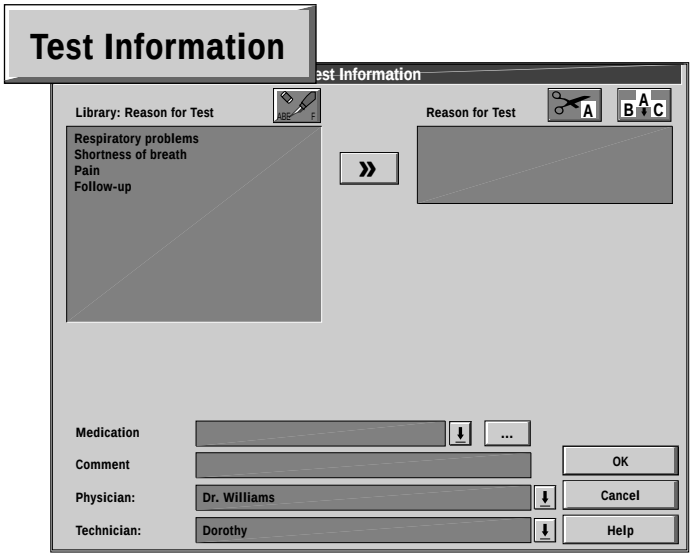


Figure 4.5-8. Test information

On the test summary page you find the test information, reasons for test, medications and patient data as well as the statistics intervals (night time, wake-up time, Statistics Intervals button).

Select Test Information.

The test information entry screen will be displayed (Figure 4.5-8).

Enter the procedure data as described in section 4.1.3.

Data Export

The icon allows you to export the most important data pertaining to the spirometry test to the clipboard or to any file. Data exported to the clipboard, for instance, can be inserted in a text file with the “Edit” —> “Paste” command.

Click .

Select either “Export data to clipboard” or “Export data to file”.

Click on OK.

Data from the clipboard can be inserted in a text file.

For data exported to a file you will have to specify the target directory and confirm it with OK.

All other report documents can be accessed directly via the table of contents, or you can page through the report.

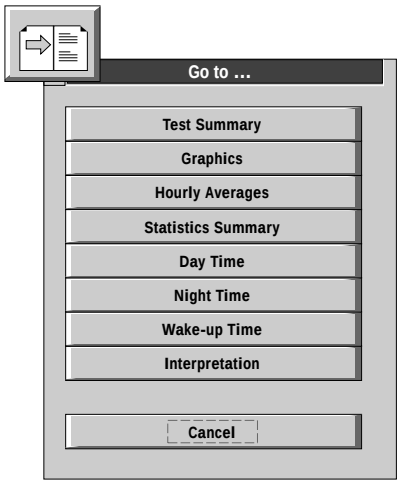


Figure 4.5-9. Table of contents of the ambulatory blood-pressure report

Click on (forward) or (backward) to page through the report.

Click on to display the table of contents of the procedure report and select the document you wish to see (Figure 4.5-9).

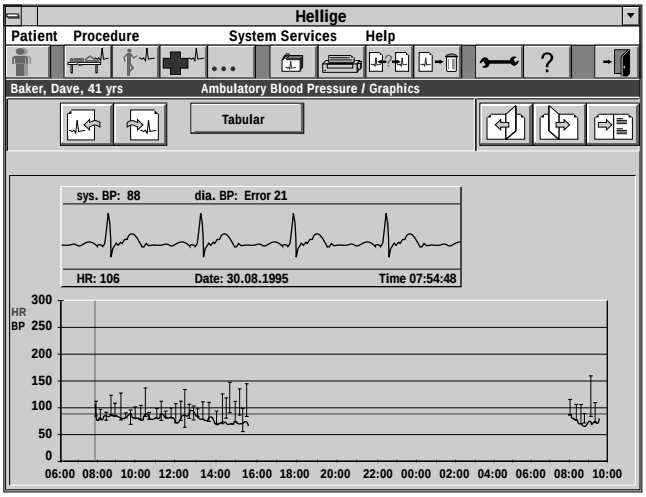


Figure 4.5-10. Graphic representation of the BP values

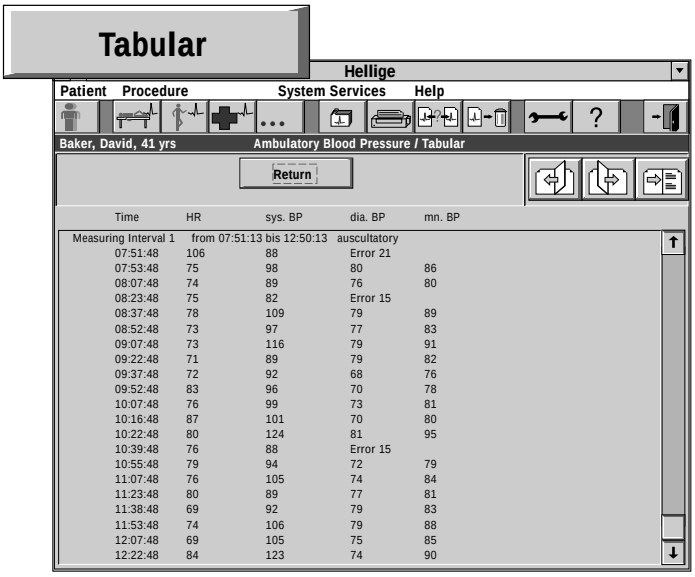
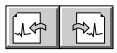


Figure 4.5-11. Tabular representation of the BP values

BP Graph

The blood-pressure graph (Figure 4.5-10) shows all blood-pressure values measured during the monitoring period.

For measurements taken with TONOPORT IVa, the ECG strips are displayed as well.

By clicking on  you can display the other ECG strips one by one, or you can cross-reference to an ECG strip by clicking on the corresponding BP measurement on the graph.

The button takes you to the BP table (Figure 4.5-11).

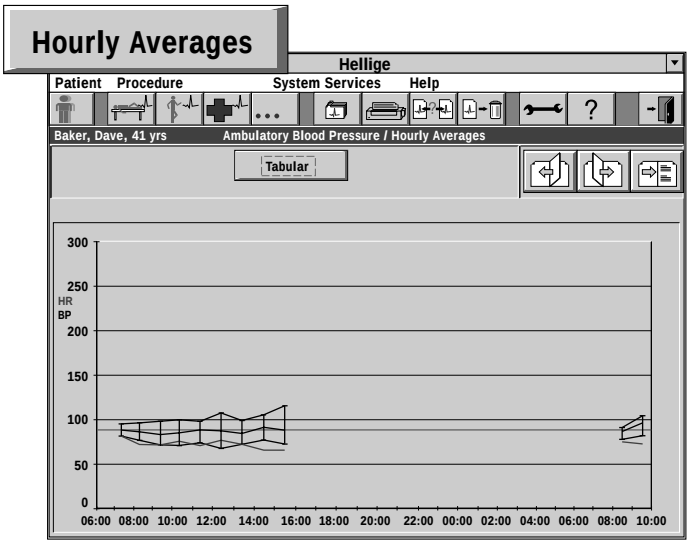


Figure 4.5-12. Hourly averages of blood pressure and heart rate

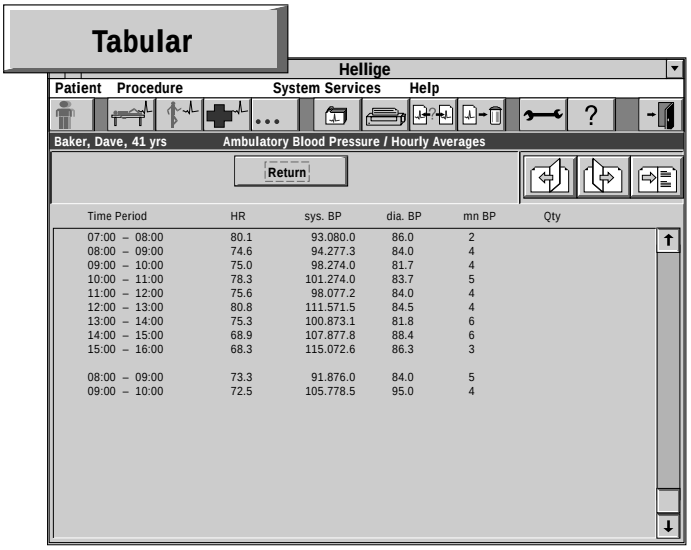


Figure 4.5-13. Hourly averages of blood pressure and heart rate

Graphic Representation of the Hourly Averages

Figure 4.5-12 shows the hourly averages of all measurements taken during the monitoring period.

Click on Tabular to display the same values in tabular form (Figure 4.5-13).

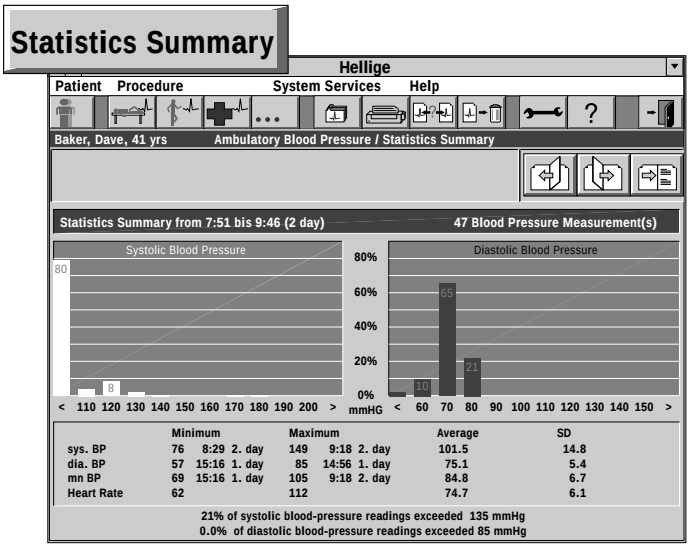


Figure 4.5-14. Statistics summary

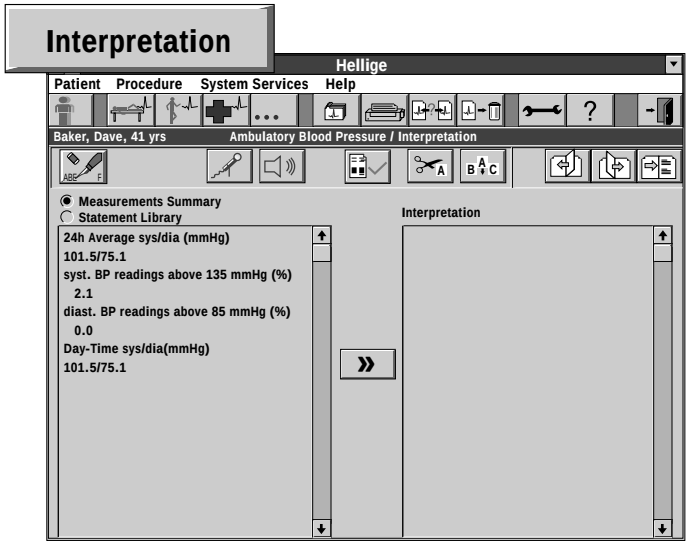


Figure 4.5-15. Interpretation

Statistics Summary

The statistics summary (Figure 4.5-14) shows one histogram each for the systolic values (left) and the diastolic values (right) as well as the frequency distribution given in percent.

The table below indicates the maximal, minimal and mean values.

The percentage of readings which exceeded the set limits is shown at the bottom.

Similar report pages exist for the day time, the night time and the wake-up time.

Interpretation

To write the test interpretation, you can choose from the system-generated measurements or from the Statement Library which, in turn, may be edited as needed.

From both “libraries” the appropriate texts can be copied into the evaluation window at right by clicking.

Select “Measurements Summary” or “Statement Library”.

Highlight the line to be copied by clicking on it, then click on [»].

An alternative method is to copy lines by double-clicking.

Confirming Tests

A test is considered confirmed, when a physician has reviewed the test evaluation and “signed” it electronically with his/her name. Tests that have been reviewed and confirmed by a physician are marked with x.

- Click on (Figure 4.5-15) to display the window where you can enter your name.

- Select the physician’s name from the list box (click on) or enter it via the keyboard.

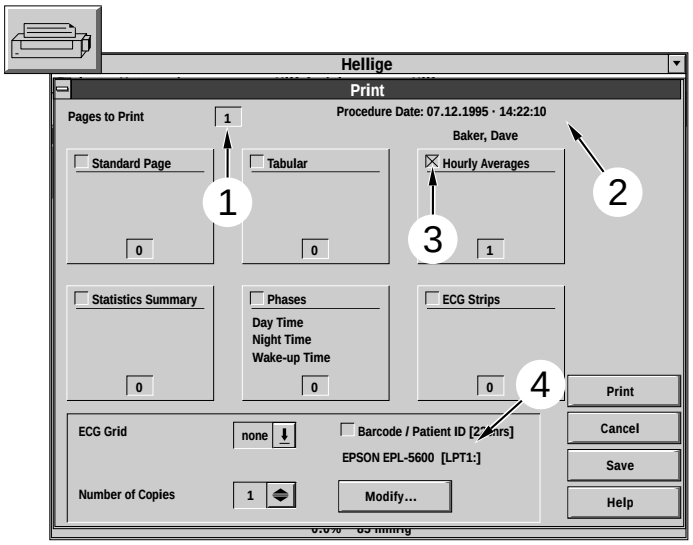


Figure 4.5-16. Printer setup screen for documentation of the ambulatory blood-pressure measurement procedure

1 Number of pages
2 Recording date
3 Document included in the printout
4 Selected printer

4.5.4 Documenting the Ambulatory Blood-Pressure Measurement Procedure

You can determine the scope of the printed report by selecting or deselecting the individual documents. This is done on a special screen (Figure 4.5-16).

Click on to display the setup screen.

If you want to include a document in the report, click on the check box next to the respective title, so that a check mark is displayed. Click again, to deselect a document. At the same time the little text box at the top indicates the number of pages to be printed (1, Figure 4.5-16). The printout is initiated with the **Print** button.
Save will save the printer setup.

Standard Page
Recording periods, medication, reason for test, comments, BP graph

Tabular
BP table

Hourly Averages
Printout of the hourly averages in the form of tables and graphs

Statistics Summary
Printout of the procedure statistics in the form of histograms, minimum, maximum and average values

Phases
Same as “Statistics Summary”, but subdivided into day time, night time and wake-up time

ECG Strips
All ECG strips consecutively.

To select another printer, click on **Modify...**. The printer setup window will open and you can click on another printer.

4.5.5 Ambulatory Blood-Pressure Measurement (Brief Operating Instructions)

Start program

Activate ambulatory blood-pressure measurement mode

Admit new patient or select patient from database

Connect recording unit to PC

Display the setup menu and select a measurement protocol

Program the recording unit

Connect recording unit to patient and initiate measurement

Connect recording unit to PC and download data

Enter the test information

Review the report documents

For your notes

4.6 Late Potentials

In this section you will learn

– some general facts about late potentials

– how to apply the electrodes and acquire the signals for late potential analysis

– how to enter procedure data (reason for test, medication, blood pressure)

– which report documents can be displayed

– how to print out the examination report

The brief operating instructions at the end of this section sum up what you have to do to record late potentials.

4.6.1 General Information

Having an amplitude in the microvolt range, late potentials occur in the terminal QRS complex and in the early ST segment. Proof of the existence of late potentials is obtained by signal averaging. For this method, the correlating QRS complexes are summed up. Since signal noise is the non-correlating portion, this method assures the required high sensitivity. A correlation coefficient can be set to any value between 1 and 99 (default: 95), thus determining the accuracy of the measurement: The higher the coefficient, the more accurate is the measurement. Furthermore, an upper noise limit for the averaged signal is preset. When the noise drops below this limit, averaging stops and the measurement begins. The analysis method used is the SIMSON method. A SIMSON algorithm is also used for determination of the QRS offset.

The ECG leads are the uncorrected, orthogonal leads X, Y and Z, they are acquired via chest electrodes attached at the corresponding pick-up points.

After the analysis, the vector diagram is displayed, showing the measured values and the average beats. Also included is the procedure summary comprising the patient data, measured values, interpretation and medication.

The overall gain of the vector representation is 20 µV/cm, which is equivalent to a 50-fold gain of the standard sensitivity of 10 mm/mV. Alternative settings selectable on the vector screen are 5, 10, 20 and 40 µV.

4.6.2 Electrode Application

Due to the small size of late-potential signals, a very careful electrode technique is required. In most cases a resting ECG will be recorded before the ECG is analyzed for late potentials. Therefore the electrodes for the 12 standard leads are applied. Late potential analysis is performed on the uncorrected leads X, Y and Z. To obtain these leads, chest electrodes C1, C3 and C5 must be moved to other sites (see below) and all 6 electrodes must be carefully applied:

– clean and degrease the skin at the application sites, using benzine

– massage the application sites with EPICONT cream until the perfusion increases (reddening of the skin)

– use only silver-silver chloride electrodes

– after electrode application, wait for about 5 minutes before acquiring the ECG signal.

Apply the electrodes as follows:

C1 on the back, opposite C2 (signal across C1 and C2 = Z)

C3 parasternal site, below the clavicula (signal across C3 and C4 = Y)

C5 at the right, opposite C6 (signal across C5 and C6 = X)

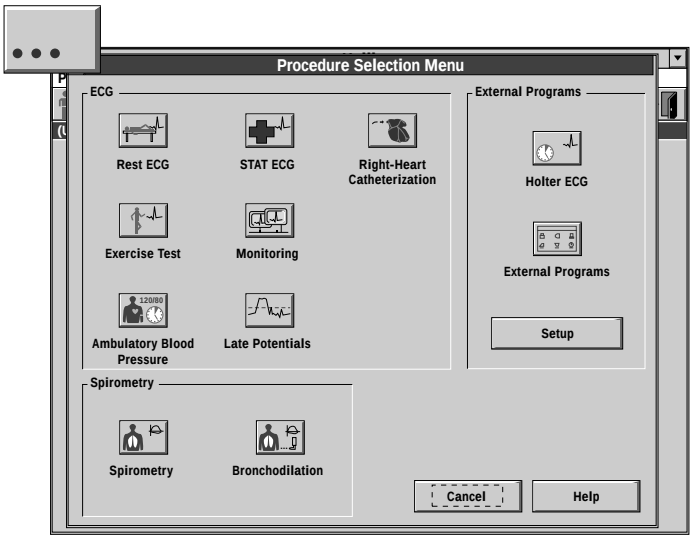


Figure 4.6-1. Procedure selection menu

4.6.3 The Late Potential Signal Acquisition Screen

The signal acquisition screen for late potential analysis is displayed with the button which is located on the procedure selection screen, unless you have reconfigured the standard icon bar (section 6 “System Services Menu”).

Entering the Test Information

Click on ... to display the procedure selection menu (Figure 4.6-1).

Click on to display the signal acquisition screen for late potential analysis.

When you have selected a patient, the test information dialog window opens (Figure 4.6-2).

Enter the test information as described in section 4.1.3.

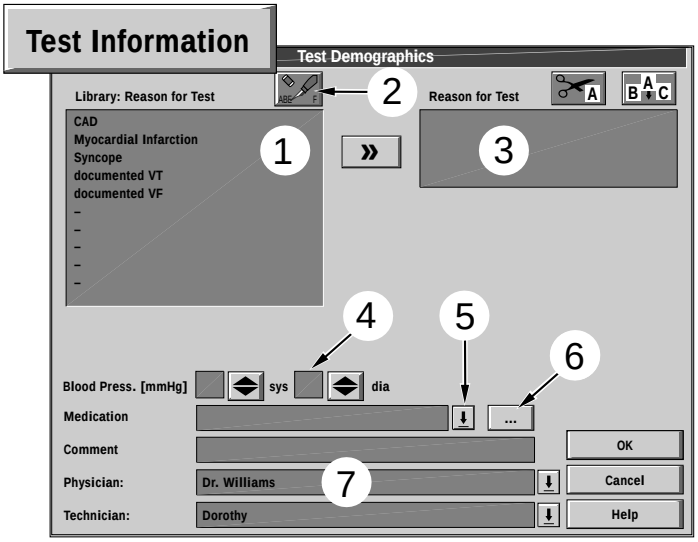


Figure 4.6-2. Test information entry screen

1 *Reason for Test library*
2 *Allows you to edit the Reason for Test library*
3 *Patient indications*
4 *Blood pressure readings*
5 *Medication selection*
6 *Allows you to select another medication and to assign drug names to medication groups*
7 *Boxes for entry of comments and of the physician’s and technician’s names*

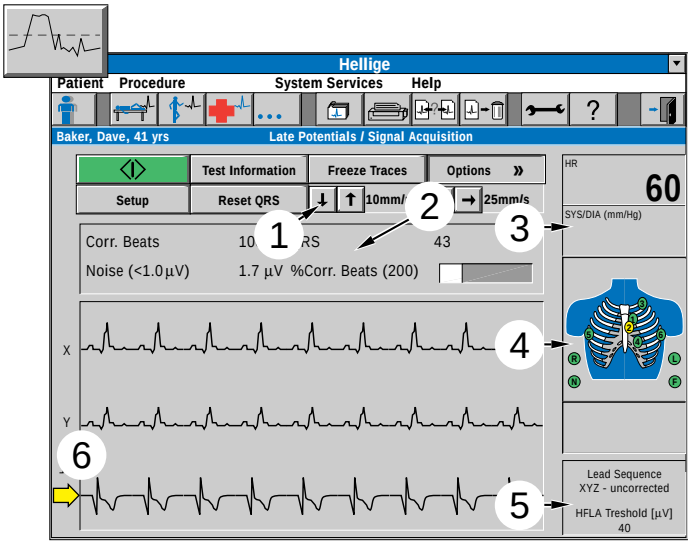


Figure 4.6-3. Signal acquisition screen for late potential analysis

1 *Control buttons*
2 *Details on late potential analysis*
3 *Current heart rate and blood-pressure readings*
4 *Applied electrodes*
green: properly applied
yellow: not properly applied
white: site not used
red: disconnected (lead break)
5 *Lead sequence*
6 *Lead impaired by poor signal quality*

The Signal Acquisition Screen

Once you close the test information window, the system will display the signal acquisition screen (Figure 4.6-3).

The signal acquisition screen shows:

– information on the ongoing analysis (2):
number of correlating beats in %
the noise limit as configured
the number of correlating QRS complexes
a bar graph illustrating the acquired correlating beats as a percentage of the required beats as configured

– the current heart rate and blood pressure readings (3) (if entered manually, section 4.1.3)

– the applied electrodes and the signal quality (4) (provided the red R electrode is applied). Furthermore an arrow (6) points to the leads which are impaired by improper electrode application or which cannot be recorded due to disconnected electrodes (or due to a break in the patient cable)

– the selected lead sequence (5)

The functions of the control buttons are explained on the following pages.

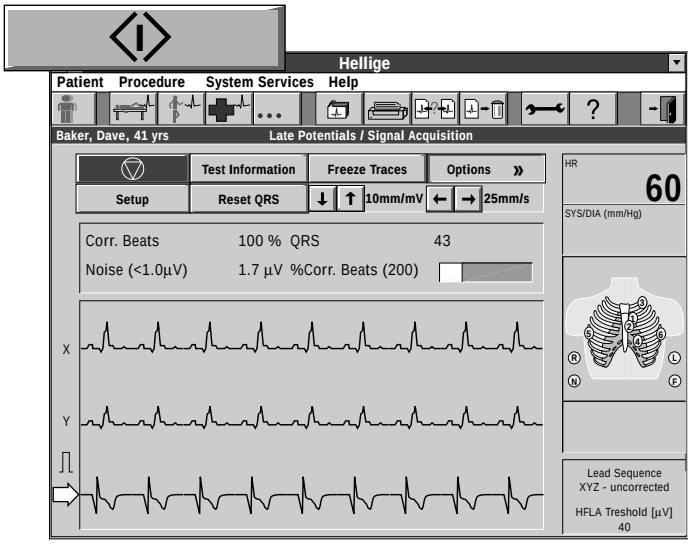


Figure 4.6-4. Late potential signal acquisition screen

> ***After every fifth correlating QRS complex the program checks whether the signal noise lies below the limit. If so, signal averaging is terminated, even when the set number of QRS complexes has not yet been reached.***

Performing a Late Potential Analysis

Click on [◊] to initiate the analysis.

The signal acquisition screen shows

– the percentage of correlating beats
– the selected noise limit in µV
– the number of correlating beats
– a bar graph representing the acquired, correlating beats as a percentage of the necessary beats

You can display the test information screen with **Test Information**.

You can stop the 2nd and 3rd ECG trace with **Freeze Traces**.

You can enable and disable the 2nd row of control buttons with **Options >>**.

You can display the setup menu (section 4.6.5) with **Setup**.

You can reject the correlating QRS complexes summed up so far and start over with **Reset QRS**.

You can change the signal size with the [↓] [↑] buttons (2.5 – 5 – 10 – 20 – 40 mm/mV).

You can change the sweep speed with the [←] [→] buttons (25 – 50 mm/s)

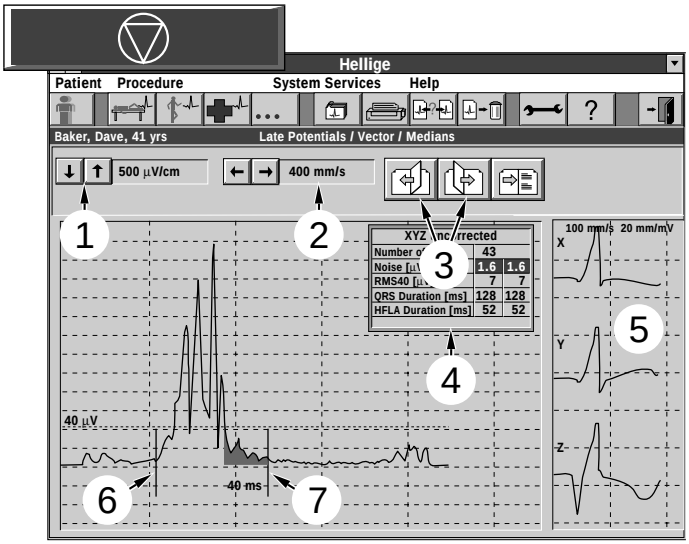


Figure 4.6-5. Vector diagram

1 *Buttons to adjust the gain*
2 *Buttons to adjust the sweep speed*
3 *Buttons to display other report documents*
4 *Parameter table*
5 *Medians (non-amplified)*
6 *QRS onset*
7 *QRS offset*

This noise value (4) may differ from the one shown on the signal acquisition screen, as it is calculated over all acquired beats.

The ECG signal acquisition stops automatically either when the signal noise drops below the preset noise limit or when the specified number of correlating complexes has been reached.

The first report screen displayed is the vector diagram (Figure 4.6-5).

Other documents of the procedure report are the interpretation (Figure 4.6-7) and the test summary (Figure 4.6-8).

Vector Diagram

Figure 4.6-5 shows the vector diagram with the marks identifying onset (6) and offset (7) of the QRS complex set by the program as well as the resulting measured values (4). The HFLA threshold is a dashed line and the HFLA duration is displayed with a different color.

The signal size can be changed with the ↓ ↑ buttons.

The sweep speed can be changed with the ← → buttons.
Furthermore, you can correct the position of QRS onset and offset as follows:

Position the cursor on the upper portion of the caliper and press the left mouse button, when the cursor turns into a double-headed arrow pointer.

Holding the mouse button depressed, drag the caliper to its new position and release the button.

The corrected values corresponding to the new caliper position appear in the right column (4) of the table.

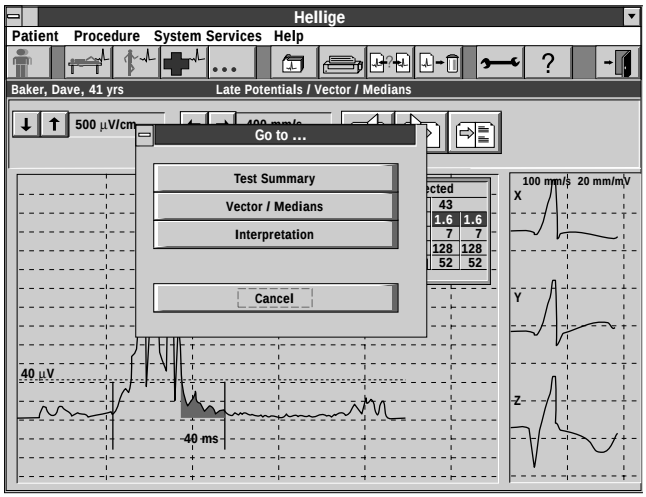


Figure 4.6-6. Table of contents of the late potential analysis report

RMS

RMS (40 ms): mean voltage in µV within the most recent 40 ms of the QRS complex.

Displaying Other Report Pages

You can display the other report pages either by paging through the report or by accessing them directly.

Click on or to page forward or backward through the report.

Click on to display the table of contents and select a document (Figure 4.6-6).

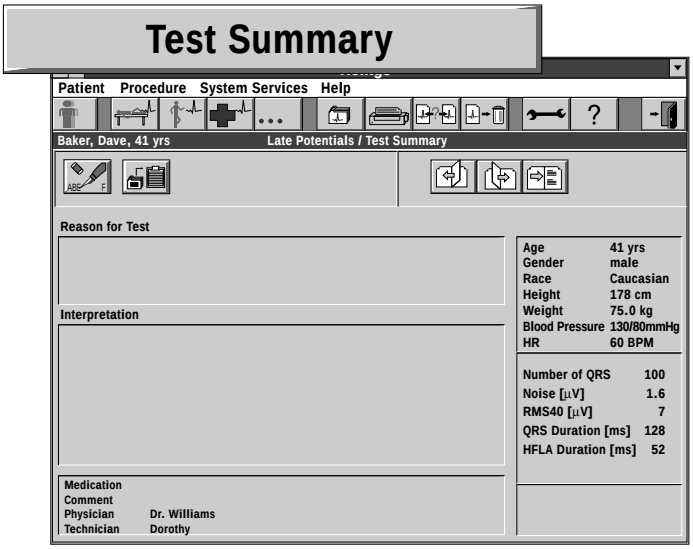


Figure 4.6-7. Test summary

Test Summary

The test summary (Figure 4.6-7) contains the following information:

Reason for Test: from the test information screen
Interpretation: excerpt of the interpretation
Medication: from the test information screen
Patient data
Measured values

If you wish to add or edit test demographics, click on the icon to display the corresponding dialog window.

Data Export

The icon allows you to export the most important data pertaining to the spirometry test to the clipboard or to any file. Data exported to the clipboard, for instance, can be inserted in a text file with the “Edit” —> “Paste” command.

Click .

Select either “Export data to clipboard” or “Export data to file”.

Click on OK.

Data from the clipboard can be inserted in a text file.

For data exported to a file you will have to specify the target directory and confirm it with OK.

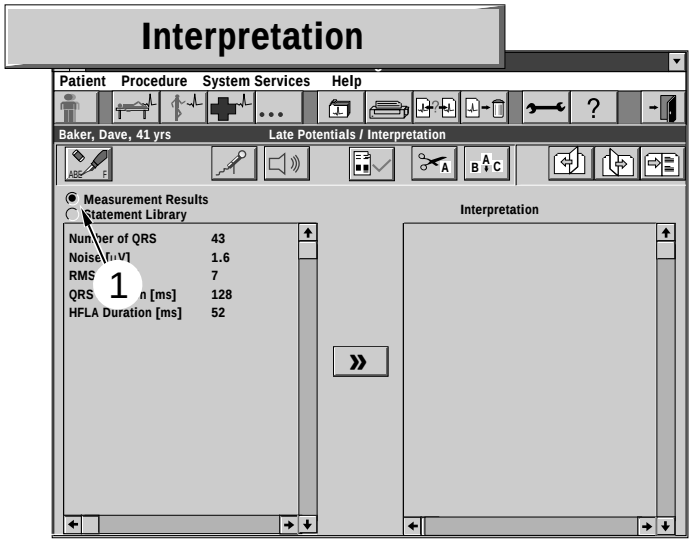


Figure 4.6-8. The interpretation screen

Interpretation

The interpretation screen is split into two windows. The one on the left shows the interpretation as derived by the system. Here you can choose between the program's measurement results and the statement library (see below). The window on the right is reserved for the physician's interpretation. Only when the procedure is assigned to a patient can the physician's interpretation be entered.

When writing the physician's interpretation you can copy the measurement results or statements from the library to the right window. Then you may edit these statements again, using the icon to cut text and the icon to reinsert the text in any other place. You may also add any comments. Furthermore, you can record a spoken comment, using the icon, provided that a sound card has been implemented in your system and that you have a microphone. This comment will be saved to the corresponding patient file. It can be played back by clicking on the icon.

- First of all, select the information to be displayed: the Measurement Results or the Statement Library (1, Figure 4.6-8).

- If you wish to copy information to the right, highlight the respective passages, then click on ».

- To enter text directly into the window on the right, move the cursor to the desired position, click the mouse button and type the text.

Confirming Tests

A test is considered confirmed, when a physician has reviewed the test evaluation and “signed” it electronically with his/her name. Tests that have been reviewed and confirmed by a physician are marked with x.

- Click on (Figure 4.6-8) to display the window where you can enter your name.

- Select the physician’s name from the list box (click on) or enter it via the keyboard.

Editing the Statement Library

When you display the statement library (1, Figure 4.6-8), the icon becomes active.

- Click on to open the window for editing the statement library.

- Enter new texts or edit existing statements via the keyboard.

- Click on to clear the window.

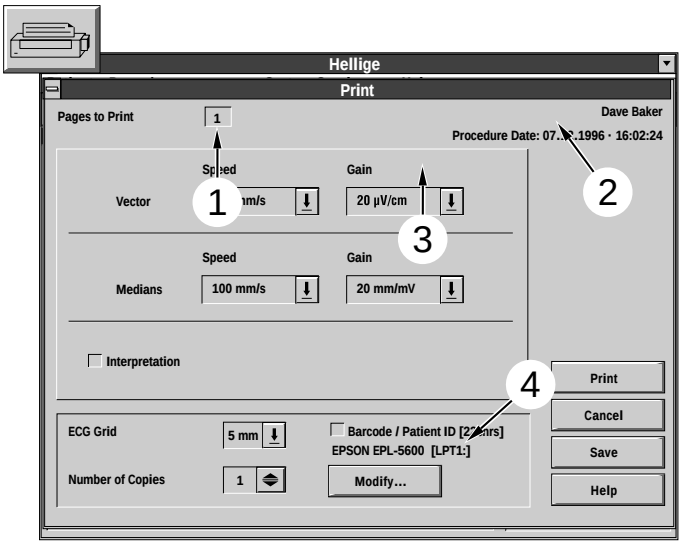


Figure 4.6-9. Printer setup screen

4.6.4 Documenting the Analysis Results

Click on the button to obtain a document of the analysis results.

The printer setup screen displays (Figure 4.6-9) where you can change the signal size and the sweep speed of the vector diagram and the median complexes before the printout.

On the same screen you include or exclude the interpretation, you select or deselect the ECG grid and you choose the number of copies as well as the printer.

Print will initiate the printer.
Save will save the printer setup.

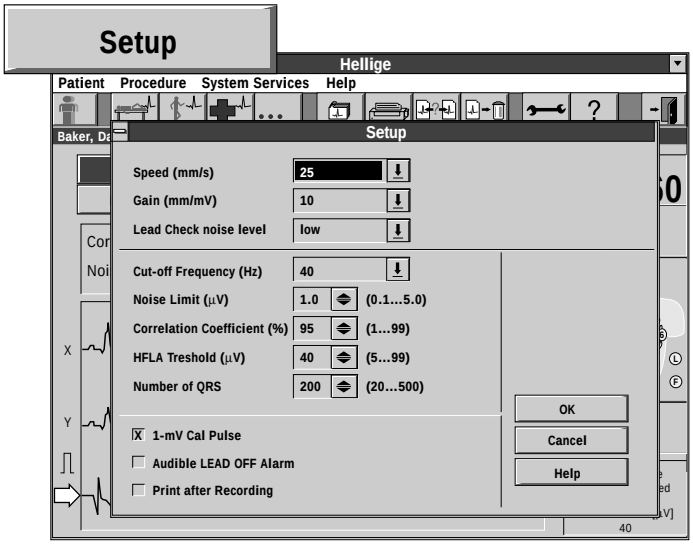


Figure 4.6-10. The defaults menu

4.6.5 Setup

Click on Options >> to display the second line of control buttons.

Click on Setup to call up the setup screen (Figure 4.6-10).

Use this screen to select your personal system settings. These settings will be saved.

Adjustments are made in three different ways:

1 There is an arrow at the end of a box. Clicking this arrow will open a window which offers various options. Select the desired setting by clicking the mouse button.

2 There is a text box next to the respective parameters. Click on this box and key in the desired text.

3 There is a check box in front of the function. Click the box to enable or disable the function (check mark = function enabled).

Speed
selects the trace sweep speed

Gain
selects the signal size (amplitude)

Lead Check noise level
This is a measure of the quality of the acquired signal (signal-to-noise ratio). When there is too much signal noise at the electrode, the electrode is displayed yellow on the signal acquisition screen. The setting that you select here (low, middle, high) changes the threshold as of which the electrode is displayed yellow (high sensitivity to noise = low threshold).

Cut-off Frequency
Adjustment of the cut-off frequency of the high-pass filter (25 Hz, 40 Hz; default: 40 Hz).

Noise Limit
Here you can enter an upper limit value for signal noise of the ECG after averaging and filtering. Any value between 0.1 and 5.0 µV is possible (default: 1.0 µV). When the signal noise falls below this limit, the system starts measuring the QRS complexes if, at the same time, at least 50 complexes have been collected.

Correlation Coefficient
The correlation coefficient entered in % is a measure of the congruence of the QRS complexes (settings between 1 and 99%, default: 95%).

HFLA Threshold
For entry of the HFLA threshold (high frequency low amplitude). Any value between 5 and 99 µV is possible (default: 40 µV). In the vector diagram this threshold is marked by a dashed line. The HFLA duration is the period of time from the end of the QRS complex towards the middle, during which the signal amplitudes were below the selected threshold.

Number of QRS
Number of QRS complexes to be averaged (also refer to “Noise Limit”). Possible settings: 20 to 500, default: 200.

1-mV Cal Pulse
Display of 1-mV calibration pulse: yes or no (check mark = yes).

Audible LEAD OFF Alarm
Audible signal when an electrode is disconnected: yes or no (check mark = yes).

Print after Recording
Printout immediately at the end of the analysis.

Click on OK (modifications are saved) or Cancel (modifications are ignored) to clear the defaults menu.

For your notes

4.7 External Programs

This section explains

– general points to note when running external programs

– how to install external programs for activation from CardioSys/Soft

4.7.1 General Information

The Marquette Hellige program has a special BDT interface for communication with external programs.

> ☞ ***Marquette Hellige is not in a position to guarantee the correct communication between the Marquette Hellige program and the external program in all cases.***

In situations where the external program and the Marquette Hellige program are operated together, the patient file is handled by the Marquette Hellige program while the procedure data are managed by the external program. At the end, the Marquette Hellige program only adopts a summary of the "external procedure" and assigns it to the procedure list of the patient concerned.

Prior to calling up an external program, you should select a patient in the Marquette Hellige program. If you wish to change to another patient during an external procedure, you have to leave the external program to select the new patient in the Marquette Hellige program.

Dialog between Marquette Hellige program and external program:

– start Marquette Hellige program

– select patient

– select external program from the procedure selection menu (the program in question must have been set up first; refer to section 4.7.2 "Setting Up External Programs")

– perform the examination (e.g., Holter ECG, sonography)

– return to the Marquette Hellige program, adopt procedure summary and assign it to the patient's procedure list

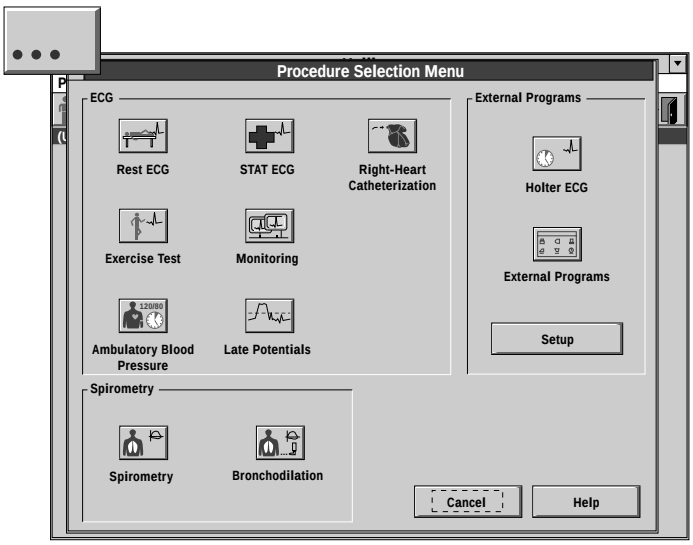


Figure 4.7-1. Procedure selection menu

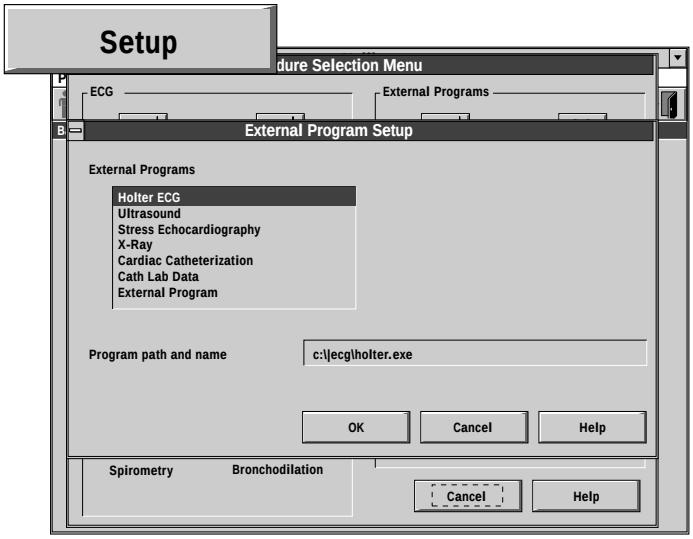


Figure 4.7-2. Setup of external programs

4.7.2 Setting Up External Programs

Click on [...] to display the procedure selection menu (Figure 4.7-1).

All icons of the external programs are dimmed, which means that they are inactive. To activate an icon, the corresponding program must be set up first.

Display the setup screen with [Setup] (Figure 4.7-2).

In the list box, click on the program to be configured, then type the program path and name in the text box below (e.g., c:\ecg\holter.exe). For “External Program” you will have to add a name for the examination under which it will be saved.

Select [OK] or [Cancel] to clear the window.

> ***When changing the external program setup, please pay attention to the compatibility with archived procedures.***

For your notes

5. Deleting Examinations, Quitting the Program

Deleting Examinations

An examination can be deleted only when it is currently displayed. This will be

– either the examination that you have just concluded

– or the examination that you have just called up from the database (3.3 “Editing Stored Tests”).

To delete an examination click . As as safety precaution you will be asked if you really wish to delete this examination. Select Yes or No, as required.

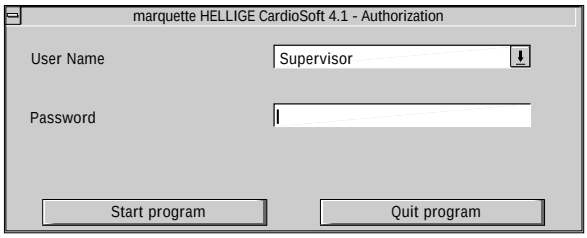


Figure 5-1. Identification window

Quitting the Program

Select .

The dialog box shown in Figure 5-1 will appear.

Click on Quit Program to exit.

For your notes

6. System Services Menu

This section explains

- how to configure the system
- how to use the voice recorder
- how to copy procedures to other storage media (e.g. for house calls)
- how to transfer resting ECGs from an ECG recorder
- how to compress data
- how to archive data
- how to save your preferred system setting under your name and how to load it

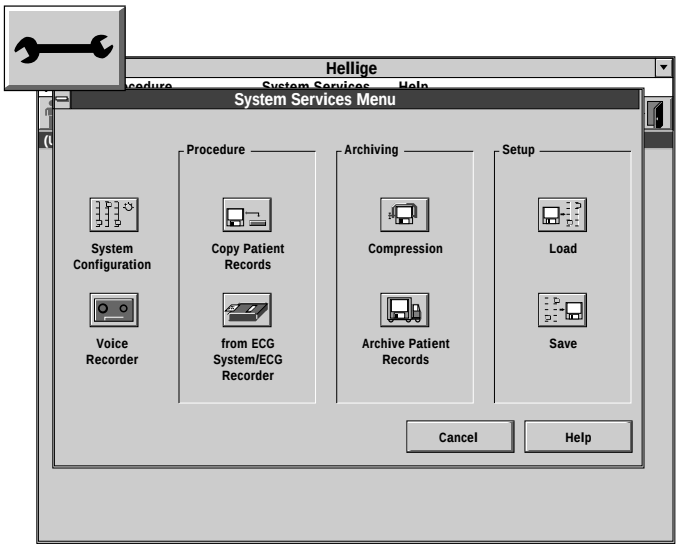


Figure 6-1. System services selection window

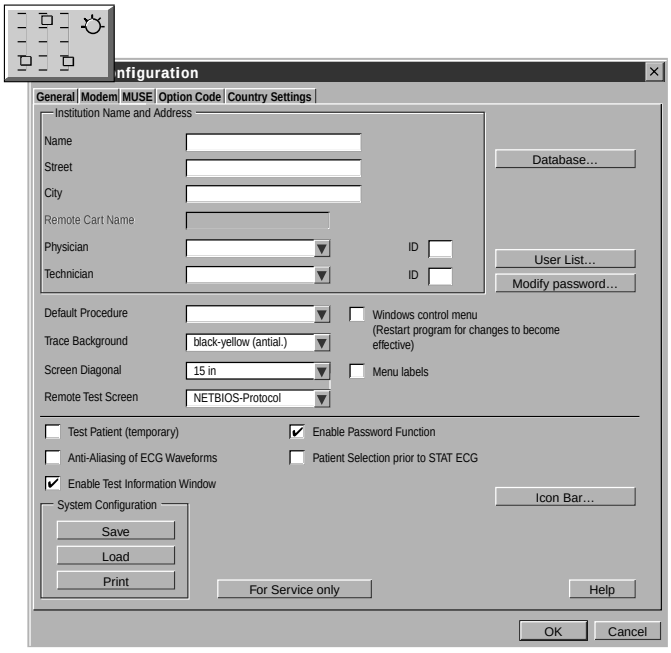


Figure 6-2. System configuration screen

6.1 System Configuration

Click : the window showing the system services opens (Figure 6-1).

Click : you will see the system configuration screen (Figure 6-2).

General Tab

Institution Name and Address

– For entry of the hospital/practice name and address (“Remote Cart Name” is enabled only when the system is connected to a network).
– For entry or selection of the physician and technician (names appear on Test Information screen) or their ID.

Default Procedure

Here you select the procedure which the system selects automatically when turned on. Click the arrow , then click the desired procedure.

Trace Background

You can select various colors for the background on which the signal traces are displayed. Click the arrow , then click the desired color.

Screen Diagonal

Select the screen size of your PC system’s monitor to assure that the traces are displayed true to scale. Click the arrow , then click the dimension.

Remote Test Screen
For selection of the network communication protocol. NETBIOS possible only when working in a network installation..

Remote Cart Name
Designates the workstation in the network (required for NETBIOS).

Test Patient (temporary)
This feature allows you to view recordings from a test patient for all test procedures. To avoid misunderstandings, you must deliberately select this feature each time you call up the program (check mark in box). Although the word _TEST is added to the patient's name, it is recommended, for reasons of safety, to open a new patient file and enter the patient name TEST.

Anti-Aliasing of ECG Waveforms
When this function is enabled [x], the displayed ECG will be smoothed.

Enable Test Information Window
When you check this box, the test demographics window will appear automatically.

Enable Password Function
User registration dialog appears at program start yes/no.

Patient Selection prior to STAT ECG
Here you choose whether or not the patient selection window will appear when you start recording a STAT ECG.

System Configuration – Save, Load, Print
– to save the configuration to a floppy
– to load the configuration from a floppy
– to print the configuration

Database
As soon as the storage capacity of the selected drive drops to a certain percentage the system displays a warning. The percentage can be entered in this window.

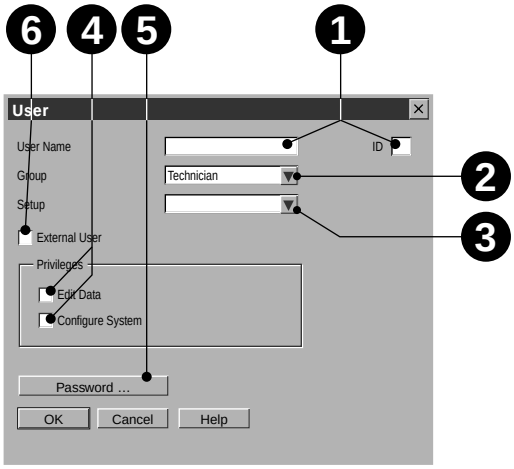


Figure 6-3. Dialog window

> ☞ ***Only the supervisor is authorized to modify the user list.***

User List ...

Via the user list, you define the persons authorized to use the program, and their rights.

Click on the User List... button to display the list of registered users (technician, physician, privileges).

To register a new user,

Click on New....

A user registration form (Figure 6-3) will appear.

Enter the user's name or ID (1).

In the "Group" list box, choose the "Technician" or "Physician" category (2).

Select the user's personel setup (see 6.6 "Loading and Saving Custom Setups" (3).

If you wish to assign privileges to the user, check the appropriate box.

Checking "Edit Data" means that the user is authorized to retrieve all stored procedures including the interpretative statements and patient data, to modify them and to delete them.

Checking "Configure System" means that the user is authorized to configure the system.

Password (5)
To change the user's password.

External User (6)
System users who wish to receive test data from other stations must be registered as "External Users". Furthermore the names and passwords of these users must be entered at the sending stations.

Windows control menu
You can choose to display the Windows control menu and the "minimize" arrow which allows you to quit the program and to shrink the window to an icon.

Menu labels
Above the icons you can display the menu labels, which allows you to click the words and select options from the drop-down menus.

Icon Bar
Here you choose the icons that will appear in the icon bar and the order of icons.

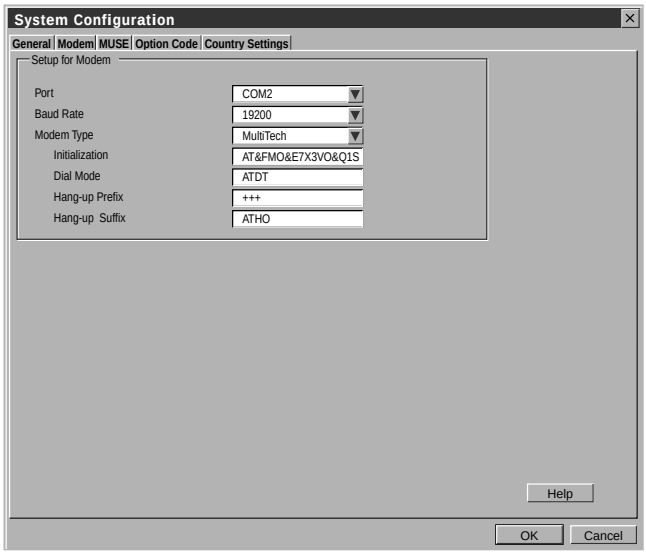


Figure 6-4. Modem setup

Warning

Only modems complying with the requirements of IEC 60950 or UL1950 may be connected to the system. Furthermore, the regulations applicable in the respective countries must be observed.
The modem must be set up inside the medically used room, but outside the patient environment.

Caution

For baud rates higher than 19200 an interface component with buffer (16550) must be installed and activated in Windows.

Modem Tab

If you wish to send data via a modem, select the port, the baud rate and the modem model here (set sender and receiver to the same baud rate).
For Multitech and ELSA modems, the system automatically enters all other necessary data. If you choose another modem, you will have to enter them yourself.

Init string for MultiTech modem (14400):
AT&FM0&E7X3V0&Q1S0=1

Init string for ELSA modem:
AT&FM0\X1X3V0S0=1

The init string must include the following commands

1. factory defaults
2. response code in digital form
3. for telephone system with extensions: display additional BUSY message
4. modem answers after 1st ring

Please observe the information given in the modem's user manual.

Here are some of the important commands:

AT	precedes each command
D	Start dialling in sender mode. The following parameters may be used in a dial command: 0-9, A-D, #, * P pulse dialing T touch tone dialing , wait for 1 s, e.g. to obtain an outside line dial tone ! flash @ wait for silent answer W wait for dial tone
&F	fetch configuration profile (copies factory defaults from the ROM to the RAM)
H0	disconnect
M0	speaker always off
M1	speaker on until connection is established
&D0	ignore DTR on-to-off transition
&Q1	use standard AT commands
Q0	modem sends response codes
Q1	modem will not send response codes
S0=1	modem will auto-answer call after first ring
V0	modem will display response codes in digital form (required setting!)
X1	modem displays CONNECT response, disables dial tone and BUSY message
X3	as X1, but modem displays BUSY message (for dialling from extensions)

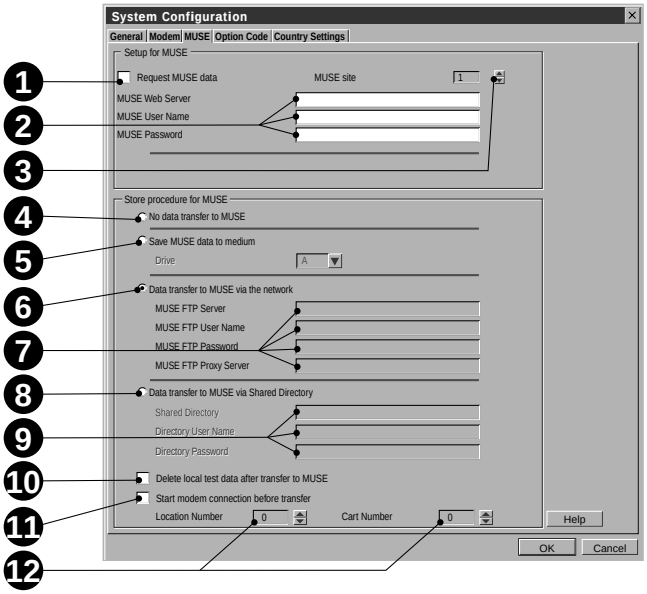


Figure 6-5. MUSE tab

> ***To transfer data to the MUSE CV database, please contact Marquette Hellige service for advice and for the necessary system setup.***
>
> *Caution*

> ***MUSE only accepts ASCII characters A to Z, 0 to 9.***

MUSE Tab

On this tab you make all selections for the transfer of data to a MUSE CV database. First of all you should obtain the following information: MUSE server network address, login name, and password. Verify that the network configuration is OK and that the Internet Explorer and Acrobat Reader are properly installed. The same applies to the modem setup when using RAS.

1 Patient data and orders are requested from MUSE.

2 Entry fields for MUSE database queries.

3 Entry field for MUSE site number.

4 Click radio button if you do not want to transfer data to MUSE.

5 Click radio button to transfer data to MUSE via a storage medium (floppy disk): select disk drive.

6 Click radio button to transfer data to MUSE via the network.

7 Entry fields for MUSE FTP server (MUSE version 5).

8 Click radio button to transfer data to MUSE via a shared directory.

9 Enter the directory names here.

10 Check box if data are to be deleted on the local hard drive after transfer to MUSE.

11 Check box to establish a modem connection.

12 Enter or select the location and cart number.

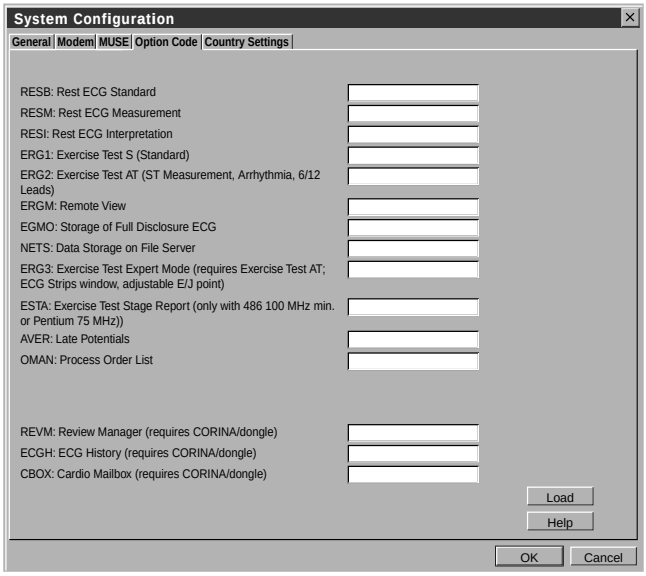

System Configuration
General
Modem
MUSE
Option Code
Country Settings
RESB: Rest ECG Standard
RESM: Rest ECG Measurement
RESI: Rest ECG Interpretation
ERG1: Exercise Test S (Standard)
ERG2: Exercise Test AT (ST Measurement, Arrhythmia, 6/12 Leads)
ERGM: Remote View
EGMO: Storage of Full Disclosure ECG
NETS: Data Storage on File Server
ERG3: Exercise Test Expert Mode (requires Exercise Test AT; ECG Strips window, adjustable E/J point)
ESTA: Exercise Test Stage Report (only with 486 100 MHz min. or Pentium 75 MHz))
AVER: Late Potentials
OMAN: Process Order List
REVM: Review Manager (requires CORINA/dongle)
ECGH: ECG History (requires CORINA/dongle)
CBOX: Cardio Mailbox (requires CORINA/dongle)
Load
Help
OK
Cancel

Figure 6-6. Option Code tab

Caution

If the Test Patient is enabled, the software options can be activated with the code number "123".

Option Code Tab

If you purchased additional software options, enter the option code(s) on this screen to activate the option(s). The code number is supplied with the purchase.

If the code numbers are stored on a disk, insert the disk and click **Load**. The code numbers will automatically be entered in the appropriate field.

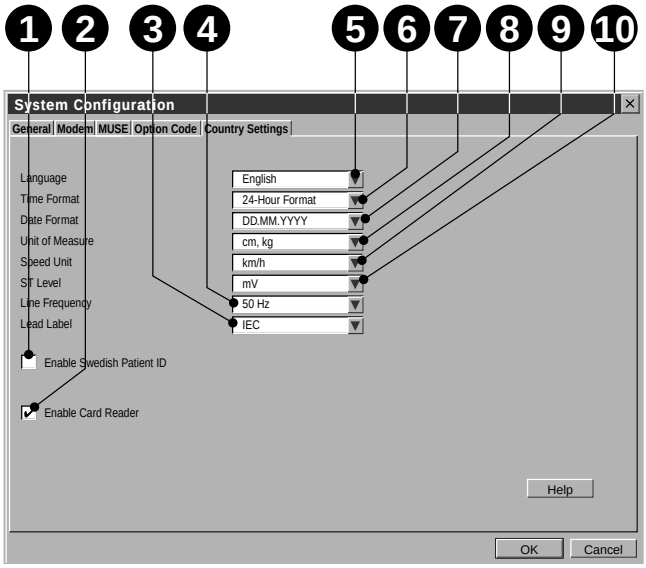


Figure 6-7. Country Settings tab

Country Settings Tab

On this screen you select all country-specific system settings.

1 Enable or disable the Swedish patient ID.

2 Enable or disable the Card Reader function (patient data acquired from patient ID card).

3 Select the electrode lead label convention: IEC or AHA.

4 Select the AC line filter frequency (50/60 Hz).

5 Select the language.

6 Select the time format.

7 Select the date format.

8 Select the units for height (cm, inches) and weight (kg, lb).

9 Select the speed unit (km/h, mph). Ensure that the same unit is selected at the treadmill.

10 Select the ST level unit (mm, mV).

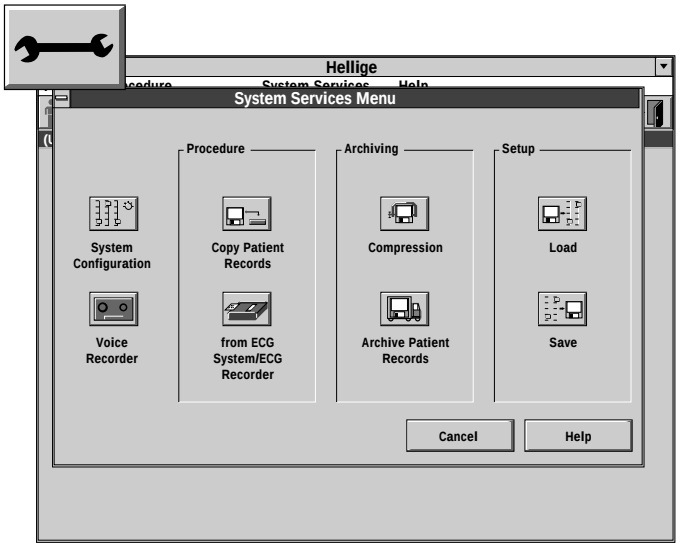


Figure 6-8. System Services Menu

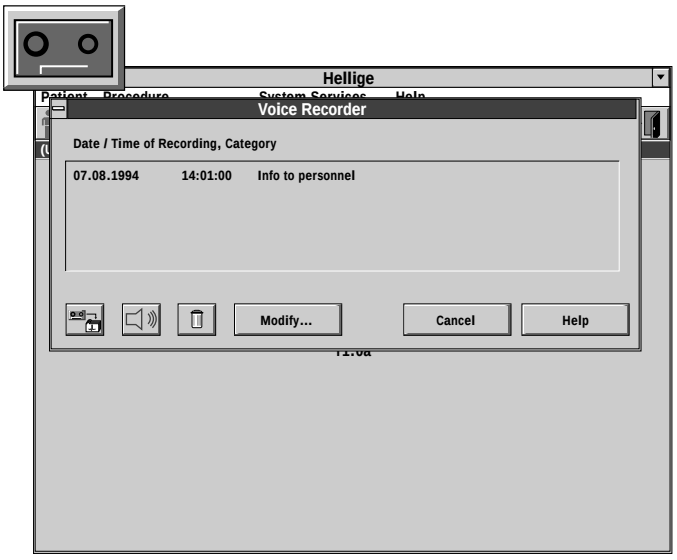


Figure 6-9. List of stored voice recordings

6.2 The Voice Recorder

The voice recorder feature allows you to record comments, save them with the date and under a specific heading, and play them back. If the program runs in a network environment, you can call up the comments from all connected stations.

Click : the window showing the system services opens (Figure 6-8).

Click the icon: you will see a list of all stored voice recordings (Figure 6-9).

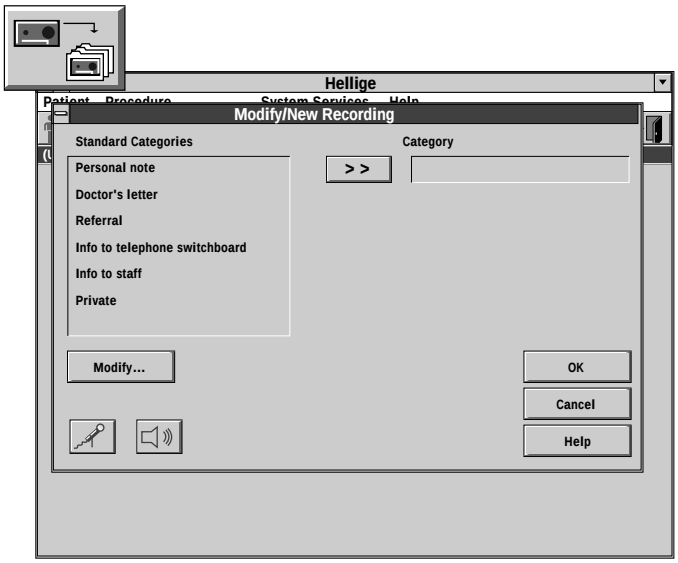


Figure 6-10. Voice recording window

Recording New Comments/Modifying Existing Comments

Click to record a new comment.

The voice recording window appears (Figure 6-10). The Standard Categories box contains up to 6 categories or headings for standard texts that you may want to record. To copy one of these standard headings into the Category box, simply double-click it in the left-hand column. It is possible to copy more than one standard heading into the Category box.

To edit one of the standard headings, highlight it and select Modify....

Entering/Modifying Standard Categories

Display the voice recording window (Figure 6-10).

Click Modify....

Move the cursor to the entry point and click.

Type the text.

Click OK to clear the window.

Creating Categories and Recording a Comment

Double-click one of the standard categories to copy it to the Category box.

As an alternative, you can also write a category directly into the Category box or add something to an existing category via the keyboard.

Click the icon and follow the instructions displayed on the screen.

Click the icon if you wish to verify the recording.

Click to quit the screen.

You will now see the table of contents, including the new recording.

Playing Back or Deleting Recordings

Click : the window showing the System Services opens.

Click the icon: you will see a list of all saved speech recordings.

Highlight the desired recording by clicking.

Click or , as required.

Click to quit the voice recorder function.

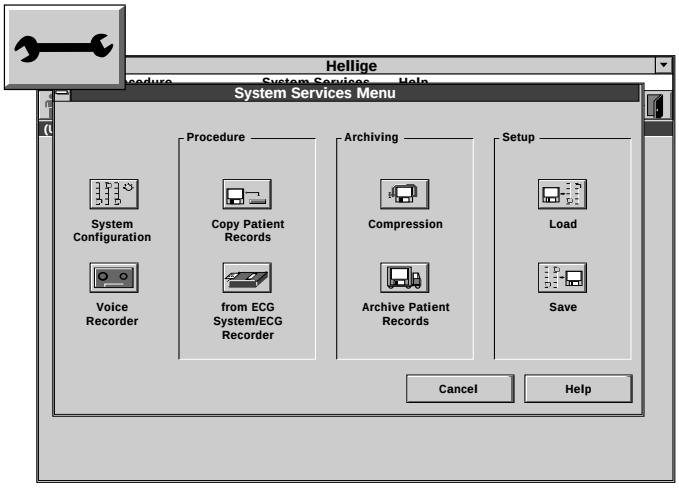


Figure 6-11. System Services Menu

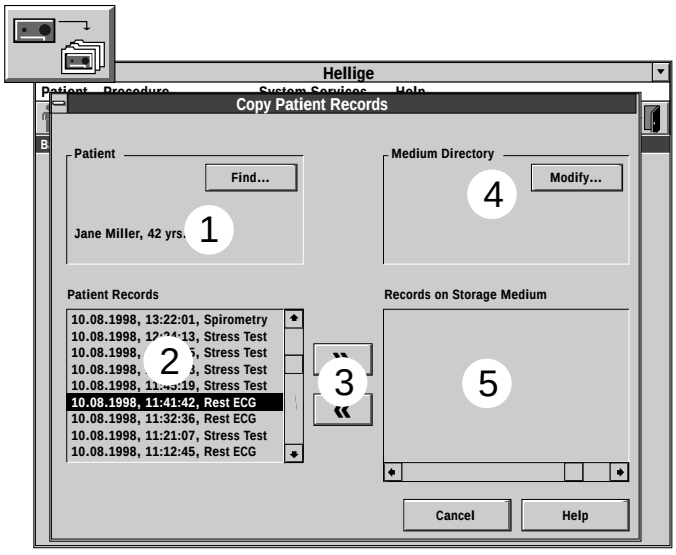


Figure 6-12. Patient records selection window (Copy Patient Records)

1 Selected patient

2 Records saved for selected patient

3 Transfer buttons

4 Storage medium directory

5 Records stored on selected storage medium

6.3 Copying Patient Records to/from Storage Medium

This function allows you to copy one or more examination procedures from the PC to another storage medium, such as magneto-optical disks (e.g., for house calls). You can also copy data from another storage medium back to your PC database. Restore procedures to your PC only if changes were made to them.

Click : the window showing the System Services opens (Figure 6-11).

Click : you will see the procedure selection window (Figure 6-12).

Copying Records from the PC to the Storage Medium

Check that the correct patient is selected.

Click Find ..., if you wish to select another patient.

This opens the patient selection window. Select a patient as described in section 3.1. All records of this patient appear in the list below.

Click the record(s) to be copied.

Check that the correct drive/directory is selected.

Click Modify..., if you wish to select another drive or directory.

☞ ***Error messages may be displayed when:***

- ***the storage medium is write-protected***
- ***the storage medium is unformatted***
- ***the storage capacity is insufficient***
- ***the storage medium is defective***

Click [OK] to clear the window.

Click [>>] to initiate transfer of the selected file(s). The copied record(s) will appear in the “Records on Storage Medium” window.

Restoring Files from the Storage Medium to the PC

Proceed as follows to copy modified records or new records to the PC:

Display the system services menu and the transfer function as described above.

Select the patient.

Select the appropriate drive/directory.

Click the record(s) to be copied.

Click [<<] to initiate transfer of the selected file(s). The copied record(s) will appear in the “Patient Records” window.

Click [Cancel] to quit the function.

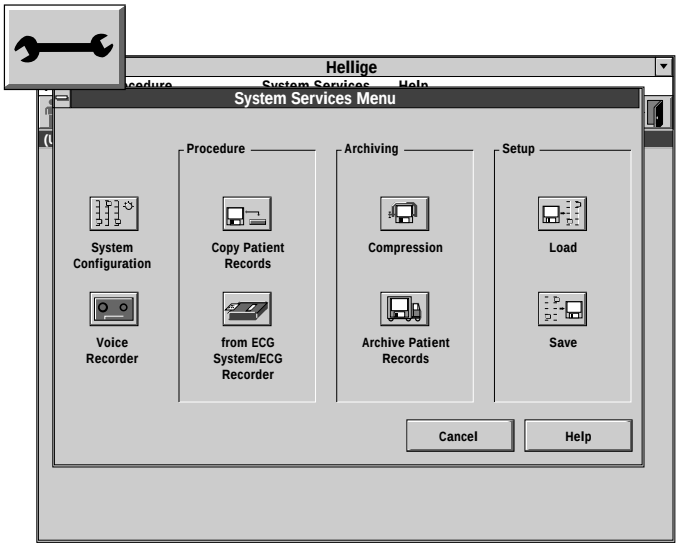


Figure 6-13. System Services Menu

> ☞ ***Some of the patient data are not transferred (e.g. the medication). Always verify the records sent from an ECG system/recorder.***

> ☞ ***If a user ID was not entered, the ECG recorders will ocasionally send the record with a number of blanks in place of the ID.***

6.4 Transferring Resting ECGs from the ECG Recorder

The system allows you to transfer ECG recordings made with a Marquette Hellige recorder (CARDIOTEST, CARDIOGNOST, CardioSmart) to the PC database.

Assigning Records to Patients

In general, the system will automatically assign the incoming records to the appropriate patients, if they exist in the database.

If the incoming record is without patient ID (and without blanks), the patient ID 000000 will be entered.

If the patient ID of the incoming record exists in the database, the record will be assigned to that patient. The patient data of the record will be updated with those in the database.

“Automatically assign procedure to patient” disabled:
If the patient ID of the incoming record does not exist in the database, the record will be registered to the list of received records and the user has to assign it manually to the correct patient.

“Automatically assign procedure to patient” enabled:
If the patient ID of the incoming record does not exist in the database, a new patient file will automatically be generated with the patient data of the incoming record and the record will be assigned to that patient.

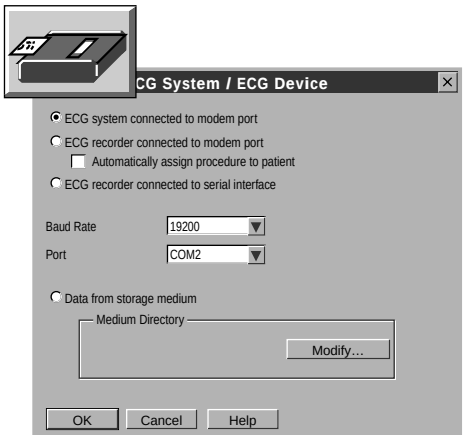


Figure 6-14. Transfer setup window (from ECG recorder)

> ***A device number (e.g. number 12) can be entered for ECG recorders, by writing "Hospital %12%" in the Hospital/Practice box.***

- Click [wrench]: the window showing the System Services opens (Figure 6-13).
- Click the [transfer] icon: you will see the transfer setup window (Figure 6-14).
- First of all, select the transfer system (ECG system = CardioSys/Soft, ECG recorder = Marquette Hellige electrocardiograph).
- Select the appropriate baud rate (19200, if possible; refer to section "Specifications" in the ECG recorder manual).
- Select the communications port [↓].
- Select the directory, if you wish to transfer data from a storage medium.
- Click [OK] to initiate file transfer, and observe the instructions displayed on the screen.
- Press the Copy key on the ECG recorder.
- Click [Cancel] to terminate ECG transfer. Figure 6-15 will be displayed where you can assign the transferred ECG(s) to the patient(s) concerned.
- Click on ECG (e.g. Resting ECG, Baker, Dave).
- Click on [Find …] to select the patient or admit a new patient, if the name does not yet exist in the database.
- Click on [<<] to assign the ECG to the patient.

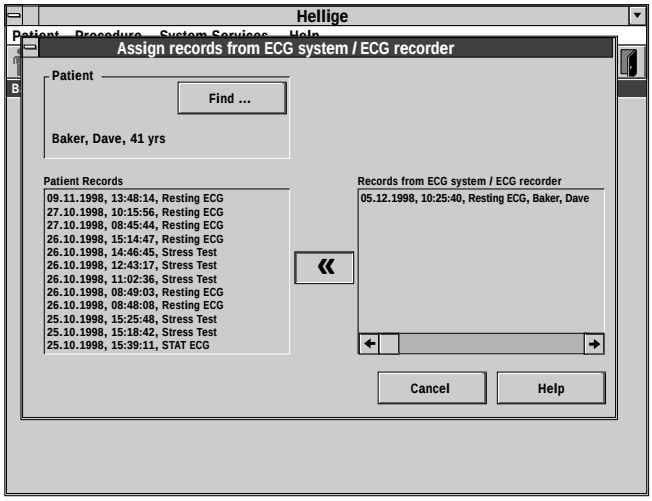


Figure 6-15. Assigning transferred ECGs

If the same resting ECG is repeatedly transmitted from CardioSmart, an error message is displayed when you attempt to assign the ECG. In this situation the redundant ECG can be deleted.

ECG Transfer via Communication Server

It is possible to simultaneously send the ECGs from several ECG recorders (max. 4) via modem to CardioSoft/CardioSys. To utilize this features, an extra PC is required as the communication server. This server is part of the network through which the ECG can be transferred to the CardioSys or CardioSoft computer and/or to a MUSE CV system. Please contact Marquette Hellige service for advice.

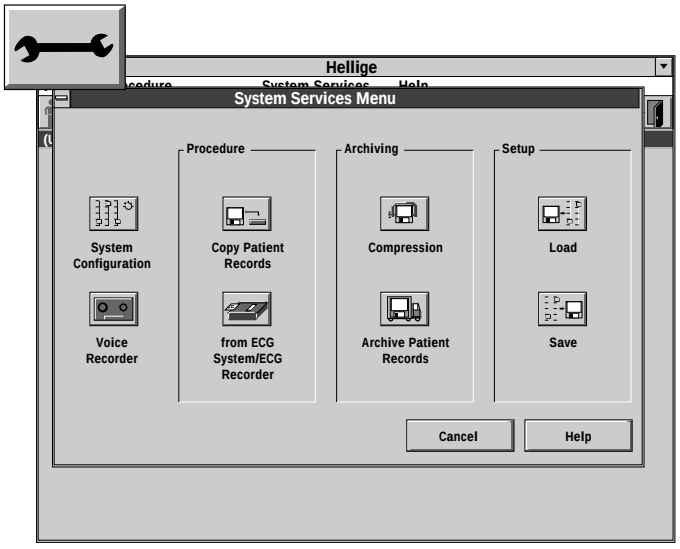


Figure 6-16. System Services Menu

> ☞ ***In a network environment, the program must be terminated at all other workstations.***

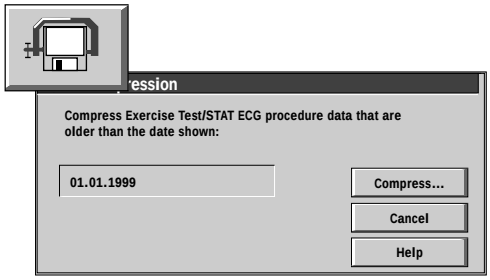


Figure 6-17. Data compression setup screen

> ☞ ***Run a backup of all data (Appendix 3) before compressing or exporting it.***

6.5 Data Compression, Archiving Patient Records

Data Compression

Older data files which are seldom used can be compressed to free storage capacity for new data files. If you call up the compressed files, they uncompress automatically. They take only a little longer than normal files to be displayed.

- Click [🔧]: the window showing the System Services opens (Figure 6-16).
- Click the [🖫] icon. The compression setup screen appears (Figure 6-17).
- Enter the procedure date up to which you want to have the files compressed.
- Click [Compress...] to initiate data compression. As a safety precaution, the system asks you if you really wish to proceed. Click [Cancel], if you decide to abort the procedure.
- Click on [Cancel] to terminate data compression.

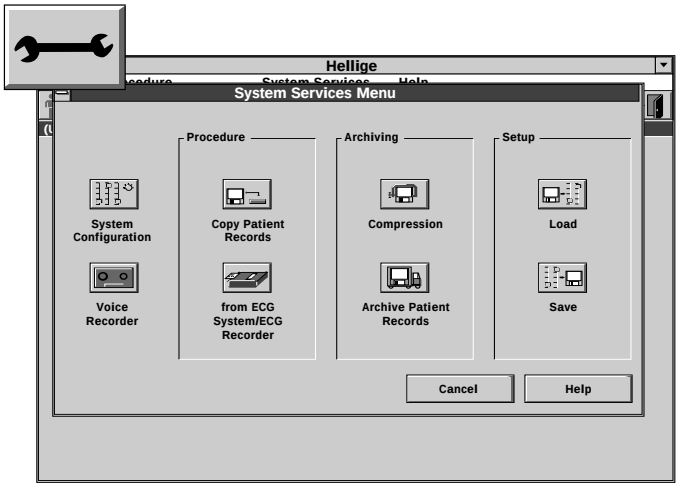


Figure 6-18. System Services Menu

> ☞ ***In a network environment, the program must be terminated at all other workstations.***

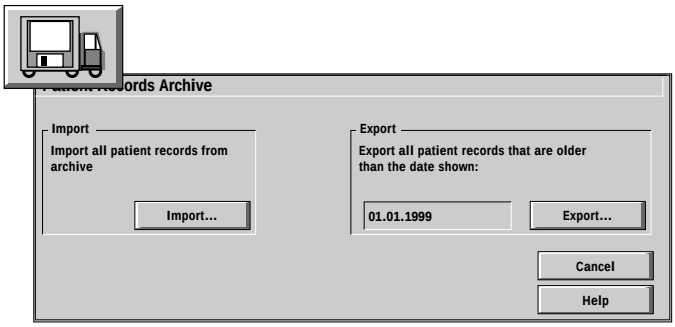


Figure 6-19. Data export setup screen

> ☞ ***In the "Virtual memory" window the "32-bit access" must be disabled.***

Archiving Patient Records (e.g. to a magneto-optical disk)

An even more efficient way to free storage capacity is the export of data to external storage media. These files are still included in the table of contents, but they are marked with an asterisk*.

If you select one of these files for display, the program tells you where they are stored. Before archived records can be transferred to MUSE, they must be restored to the system.

- Click [🔧]: the window showing the System Services opens (Figure 6-18).
- Click the [🚚] icon. The archive setup screen appears (Figure 6-19).
- Enter the date up to which you want to have the files exported.
- Click [Export...].
- Insert the storage medium and, after the archive procedure, label it with the number displayed.
- Select the target drive (e.g. d:\). Do not export data to the root directory, but to the subdirectory d:\data, for instance.
- Click [OK] to initate file transfer, and observe the instructions displayed on the screen.
- Proceed in a similar manner to import files into the PC system, using the [Import...] functions.

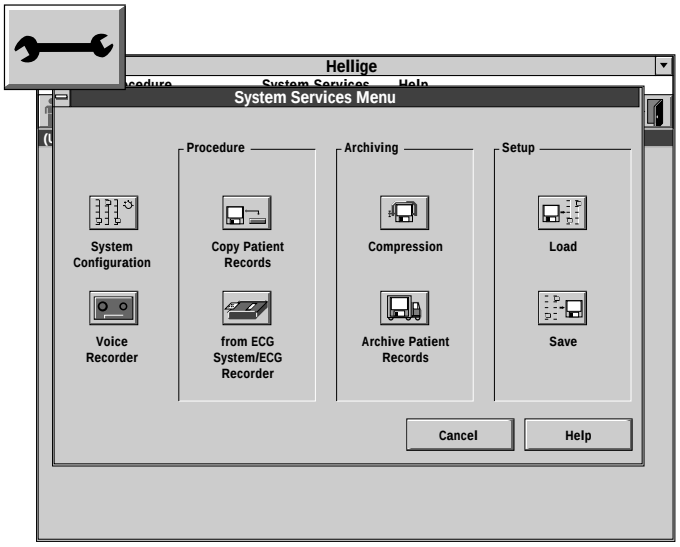


Figure 6-20. System Services Menu

> ☞ ***It is not possible to save exercise protocols or test phases.***

> ☞ ***Before loading a stored system setup you must save the setup currently active.***

> ☞ ***When reactivating the factory settings, the exercise test protocols and phases that you created yourself will be deleted with some ergometer models.***

6.6 Saving and Loading Custom Setups

The program allows you to save setups and text libraries under a user or ward name and to quickly load these settings whenever needed (exceptions to this rule are explained at the end of this chapter). With this feature you can adjust the system to suit a specific user's requirements in a matter of seconds. When running in a network environment, the program settings, including the factory settings, can be called up at any connected station.

Click [🔧]: the window showing the System Services opens (Figure 6-20).

Click [💾] to save the setup and [📂] to load a setup.

Save

1. Select the drive.
2. In the "Save As" field, enter the name for this setup.
3. Click the [Save] button.

Load

1. Select the drive.
2. Click on the setup name.
3. Click the [Load] button to load the setup.

The following parameters cannot be loaded, saved or reset to factory settings:

exercise test	– ergometer model – ergometer port – remote view – BP monitor model – BP monitor port – thermal printer port
spirometry	– ambient conditions – respiration sensor port
ambulatory blood pressure	– BP monitor port
system configuration/ general	– access password – default mode – trace background – screen diagonal – station name – physician – user – patient selection with card reader only – test patient – icon bar configuration – option codes – Windows configuration – baud rate/electrocardiograph interface

7. Cleaning, Disinfection and Maintenance

7.1 Instrument Surface

* Before cleaning and disinfecting the device, disconnect it from the power line.

* Clean the instrument surface with a cloth moistened in a cleaning solution. Take care that the solution does not enter the device. All hospital-grade cleaning solutions and disinfectants containing up to 70% alcohol are suitable.

* Disinfectants with a phenol base or peroxide compounds are not suitable for disinfection of the instrument surface.

7.2 Patient Cable and Electrodes

* Disconnect the cable from the device before cleaning or disinfecting it. To do this, pull on the plug, not on the cable itself.

* Rub the cable clean with a cloth soaked in soapy water. To disinfect the cable, rub it down with disinfectant. Do not immerse the cable in liquids!

In addition to the information below observe the instructions for use enclosed with the electrodes.

* Discard disposable electrodes immediately after use to prevent their being reused.

* Clean reusable electrodes immediately upon removal from the patient.

* Peel off the adhesive foil before cleaning them (residual adhesive can be removed with benzine).

* Use warm water and a small brush to remove electrode cream. Do not use pointed metal objects to remove solid particles of dirt from the electrodes.

* Disinfect the electrodes with alcohol-free disinfectants. Make sure that plugs and sockets do not become wet.

* Use only gas to sterilize the electrodes (frequently sterilizing the electrodes with ethylene oxide shortens the life of the plastic material).

* For information on cleaning, disinfection and sterilization of other sensors and transducers, please refer to the instructions for use included with these devices.

7.3 Respiration Flow Sensor LF 501

Please refer to the Operator's Manual of the Respiration Flow Sensor LF 501 for more details on cleaning and disinfection.

Cleanliness and hygiene of the sensor is of the utmost importance as the patients breathe in and out through the sensor during the test. Use a new mouthpiece for each new patient. The use of mouthpieces with bacteria filters is imperative!

When using mouthpieces with bacteria filter in compliance with their instructions for use, it is not necessary to clean and disinfect the sensor after each measurement.

This applies on the condition that the patient does not suffer from infections of the respiratory tract and that not more than 15 respirations are measured on the patient.

When a test is performed on a patient with a manifest or suspected infection of the respiratory tract, cleaning and disinfection of the sensor is imperative.

For average use of the sensor, i.e., up to 5 tests of patients with no infections of the respiratory tract per day, it is sufficient to clean and disinfect the sensor once a day.

Even when the sensor is not in use, we recommend that it be cleaned and disinfected once a week.

The Respiration Flow Sensor LF 501 does not require routine maintenance.

7.4 Maintenance

Checks Before Each Use

Visually inspect the system, all cables, and electrodes for signs of mechanical damage before each use.

If you detect defects or malfunctions which may impair the patient's or the user's safety, the system must be repaired before being used again.

The system does not require other regular maintenance.

Technical Inspections

For safety, the devices require regular maintenance. To ensure functional and operational safety of the system, technical inspections should be carried out annually.

These inspections should be referred to independent persons with adequate training and experience.

Within the framework of a service contract Marquette Hellige service representatives would be pleased to carry out these preventive maintenance inspections for you.

The Technical Inspections include:

* visual inspection of the device and accessories for mechanical damage that may impair their function
* verification of the safety-related device labelling for readability
* verification of the device platform
* measurement of the resistance of the non-fused earthed conductor and of the equivalent leakage current according to the local regulations.

The system does not require other regular maintenance inspections.

For your notes

8. Troubleshooting Tips

System Messages

Message: CORINA not connected/not switched on! (audible alarm sounds)

Remedy:
- Exit program (chapter 5) and start over (section 2.4).
- Delete the entry “load=…” in the [window] section of the WIN.INI file.
- Implement additional parallel interface for CORINA.
- If the message recurs, contact the nearest sales-service office.

Message: Internal CORINA malfunction! (at the same time, the system emits 3 beeps)

Remedy:
- Contact the nearest sales-service office.

Message: CORINA malfunction: Data transfer!

Remedy:
- Exit program (chapter 5) and start over (section 2.4).
- If the message recurs, contact the nearest sales-service office.

Malfunctions

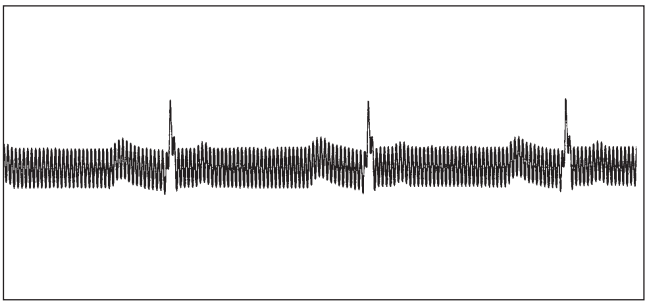


Figure 8-1. Regular AC interference

Interference: regular AC interference (50/60 Hz)

Cause: interference from the power line

Remedy:
- Ground bed and system, verify electrode placement.
- Switch on AC filter, if necessary.

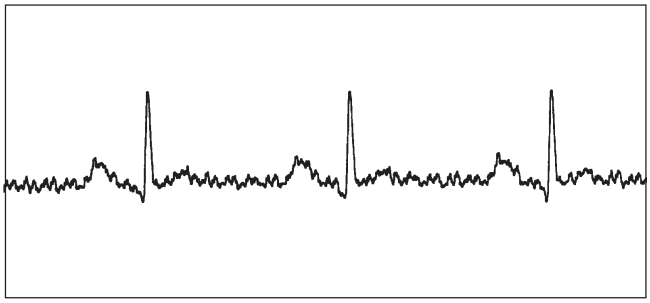


Figure 8-2. Irregular AC interference

Interference: irregular interference signals

Cause: muscle artifact due to patient movements, trembling, hiccough, coughing

Remedy:
- The patient should be warm enough and rest comfortably (place cushions under patient's knees or arms).
- Divert patient's attention or distract him/her.
- Switch on muscle filter, if necessary.

9. Technical Specifications

ECG Processing

Lead selection

manual selection of individual lead sequences or automatic lead sequencing

* lead sequences: EINTHOVEN, GOLDBERGER, WILSON, NEHB, CABRERA lead sequence and custom-configured sequences

Automatic functions

assist and simplify system operation with

* automatic blocking function
* formatted reports
* automatic baseline adjustment
* cubic spline algorithm for compensation of variations in polarization voltage

Heart rate readout

derivation of the heart rate from all ECG signals:

* display range 30 to 300 BPM (measurement and interpretation up to 240 BPM)
* display update with every heart beat, or every 2 s

Signal transmission

Patient signal input to recording

simultaneous transmission of all electrode signals to digital signal processing system after lead derivation and digitization; a muscle filter and an AC filter can be activated simultaneously for all leads, pacing pulse detection, automatic or manual sensitivity adjustment, automatic baseline adjustment, drift compensation by cubic spline

* lower cut-off frequency (-3-dB limits) 0.04 Hz, corresponding to a time constant of 4 s
* upper cut-off frequency (-3-dB limits)
  resting ECG/STAT ECG: 150 Hz (IEC/AHA)
  stress-test: 75 Hz (IEC)
* signal sampling rate: 1000/s
* resolution, referred to the input: 5 µV
* sensitivity simultaneously adjustable for all leads:
  40 – 20 – 10 – 5 mm/mV
* 3-dB drop of the amplitude frequency response with active muscle filter (low-pass) at about 40 Hz
* with active AC filter identification and compensation of regular 50-Hz or 60-Hz frequency components (depending on frequency of power line): attenuation >40 dB
* non-linear distortion better than specified in IEC and AHA recommendations
* identification of pacing pulses in C2 or another C electrode and marks in all channels for signals referred to patient input: duration > 0.1 ms, amplitude > 5 mV
* noise of signal transmission path less than specified in IEC and AHA recommendations: < 2.5 µV rms
* common-mode rejection for 50 or 60-Hz signals (depending on model) with AC filter enabled >140 dB

ECG calibration

automatic recording of a defined voltage jump, valid for all channels

* calibration voltage, referred to the ECG signal input: 1 mV

Baseline

automatic adjustment to the optimal writing range, in dependance of signal amplitude

Cubic Spline

automatic compensation of baseline fluctuations caused by variations of the polarization voltage at the pick-up electrodes

Blocking

automatic rapid charge reversal of the coupling capacitors in the preamplifiers upon electrode application

ECG signal input

isolated patient connection type CF according to IEC, all pick-up electrode connections and N-connection high-voltage-proof, electrodes are monitored for signal quality and lead breaks

* electrode connections for R, L, F, N, C1 to C6, Nax, Nst, Nap (=C4)

* input impedance for differential signals between any two electrodes at 10 Hz > 10 MOhms

* input impedance for common-mode signals referred to N up to 60 Hz > 50 MOhms

* dynamic range for differential signals between any electrode connections ±10 mV for AC voltage, ±600 mV for superimposed DC voltage (polarization voltage)

* dynamic range for common-mode signals referred to N ±1V, referred to chassis 264 V rms

* quiescent input current via any electrode connection for 1-kOhm termination referred to N < 50 nA

* patient leakage current (rms values) according to IEC class CF: in normal condition <10 µA, in single-fault condition (e.g., patient in contact with line voltage) <20 µA

non-destructive load at pick-up electrode connections and N-connection referred to N ±50 V, referred to chassis ±1500 V

* pulse voltage resistance of all pick-up electrode connections and N-connection referred to chassis of either polarity (e.g., defibrillation) 5000 V

ECG signal output

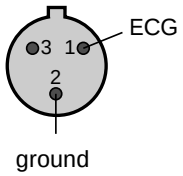
ECG signal output for synchronization of ultrasonic units (not for diagnostic purposes)

The initialization that takes place each time a test mode is started briefly blanks the ECG signal at the analog output.

The medical system created by connection of external devices must fulfill the requirements of standard IEC 60601-1-1/ EN 60601-1-1

– ECG lead selectable
– electrically isolated (±1500 V referred to chassis)
– input signal of 1 mV results in 1-Volt output signal
– U_{outmax} ±10 V
– offset accuracy < 300 mV (typical, full scale)
– accuracy over entire width < 3% (typical)
– R_l min. 2 kOhms
– delay <10 ms
– pacing pulses removed by filtering

(The low-pass characteristic of the input stage of the connected trigger detection circuit should be f_g <500 Hz.)



Lead fail detection

Visual and audible indication of disconnected electrodes and broken leads. Individual monitoring of each electrode.

Interfaces

PS/2 mouse

Serial interface

COM1
COM2 ergometer, treadmill
COM3 Respiration Flow Sensor LF 501
COM4 unassigned, free for ECG recorder, for instance

Parallel interface

LPT1 printer
LPT2 CORINA

Printer

EPSON EPL 5700 with at least 4 MB of memory
HP 6P with at least 5 MB of memory
(only the printer modified by Marquette Hellige is allowed to be installed on the system cart)

Keyboard

CHERRY keyboard G 81-3000
with card reader: CHERRY G 80-1501
Marquette Hellige function keypad for routine operation during exercise test

Monitor

15-inch or 17-inch monitors can be connected
(only the monitor models supplied by Marquette Hellige are allowed to be installed on the system cart)

Power supply

from the power line, system design in compliance with IEC 60601 protection class I

Version for 230 V

* rated voltage range 220 to 240 VAC, 50/60 Hz
* operating voltage range 198 to 264 V, 49 to 63 Hz
* rated current with 17 inch monitor 1.5 A
* power consumption
  w/o. monitor 60 W
  with 15-inch monitor 130 W
  with 17-inch monitor 140 W

Version for 115 V

* rated voltage range 110 to 120 VAC, 50/60 Hz
* operating voltage range 98 to 132 V, 49 to 63 Hz
* rated current with 17 inch monitor 2.5 A
* power consumption
  w/o. monitor 60 W
  with 15-inch monitor 130 W
  with 17-inch monitor 140 W

Environment

Operation

* ambient temperature between +10 and +40 °C
* rel. humidity between 30 and 75%
* atmospheric pressure between 700 and 1060 hPa

Storage and transport

* ambient temperature between -30 and +60 °C
* rel. humidity between 20 and 95%
* atmospheric pressure between 500 and 1060 hPa

Dimensions and weight

height:	1150	mm
width:	680	mm
depth:	825	mm
weight:	60	kg (w/o. monitor and printer)

For your notes

10. Equipment

Subject to modification. Always refer to latest list of accessories!

101 121 06 CardioSys ECG analysis system including system cart, PC, 15-inch monitor, keyboard, mouse, standard software package and exercise test S software

Accessories

General accessories

227 498 02 Operator's Manual

System carts

202 306 40 System cart, 230-V version, with pump for electrode application system, incl. Windows NT 4.0, language: optional

202 306 41 System cart, 230-V version, without pump for electrode application system, incl. Windows NT 4.0, language: optional

202 306 42 System cart, 230-V version, with analog output and pump for electrode application system, incl. Windows NT 4.0, language: optional

202 306 43 System cart, 230-V version, with analog output, incl. Windows NT 4.0, language: optional

Optional PC components

701 180 72	Network board
701 249 16	Controller for MO or streamer drive
384 018 07	640 MB MO drive
384 018 75	2.4 GB streamer drive

Peripheral devices

701 247 02	Keyboard, English
220 092 07	Function keyboard for exercise tests, English
220 093 07	Function keyboard for exercise tests, English, with barcode reader
701 181 34	Mouse
701 245 03	Monitor, 15"
701 245 11	Monitor, 17"
701 242 79	Laser printer EPSON EPL 5700
834 005 09	Toner cartridge for EPL 5700
701 249 25	Thermal printer AR 200
226 169 01	Paper for thermal printer AR 200
384 018 92	Network option PCI (upgrade)
384 015 80	Network option BNC (requires system PC with network board 701 180 66)
384 017 33	Network option TP (requires system PC with network board 701 180 72)

Optional software programs

455 023 01	Resting ECG measurement
455 024 01	Resting ECG interpretation
455 039 01	Review Manager
455 040 01	ECG History
455 025 01	Exercise test SW, 3-lead ECG
455 026 01	Exercise test SW upgrade, 12-lead ECG
455 027 01	Full-disclosure ECG storage, data handling, data compression
455 029 01	Monitoring of remote stress-test stations
455 030 01	Storage on central file server
455 032 01	Exercise test, expert mode
455 033 01	Exercise test, in-test reports
455 041 01	Cardio mailbox
455 034 01	Task list processing
455 035 01	Late potential analysis

System cart accessories

915 418 12	Adapter 9/25 pole, D-SUB interface
915 418 11	Adapter (AT keyboard to PS2)
919 202 47	Mouse pad
701 244 01	Printer cart

Cables

919 062 00	Power cord, Euro
919 203 37	Power cord, UK
401855-107	Power cord, CH
919 201 81	Power cord, USA
919 200 37	Potential equalization cable
223 330 03	Connection cable for M 700
223 366 03	Connection cable for EC 1200
223 362 03	Connection cable for EC 560/ECB 561/ CardioSmart
223 368 01	Connection cable for TM 400 E
223 380 01	Connection cable for ERGOLINE ERG 900
223 381 01	Connection cable for SUNTECH 4240
223 390 01	Connection cable for T2000 (RS 422)
700609-001	Connection cable for T2000 (RS 232)
223 372 01	Connection cable for EK 51, EK 56, EK 512
223 298 04	Network connection cable
223 363 03	Connection cable for bosotron BP monitor

Patient Cables

223 418 01	Patient trunk cable, 10-lead, IEC Multi-Link, 2.2 m
223 418 02	Patient trunk cable, 10-lead, AHA Multi-Link, 2.2 m
223 418 06	Patient trunk cable, 10-lead, IEC Multi-Link, 4.5 m
223 418 07	Patient trunk cable, 10-lead, AHA Multi-Link, 4.5 m
384 018 16	Set of 10 leadwires, 4-mm connector, defib-protected, IEC
384 018 17	Set of 10 leadwires, 4-mm connector, defib-protected, AHA

Electrodes

217 225 03	Adhesive electrode for babies, 13 mm diameter, with 4-mm connector, 60-cm lead, to be attached with adhesive rings 927 224 00
217 110 03	Adhesive electrode for children, 22 mm diameter, 4-mm connector, to be attached with adhesive rings 217 123 01
217 320 01	Adhesive electrode for children, 22 mm diameter, with press-stud connector, to be attached with adhesive rings 217 123 01
217 321 01	Adhesive electrode for adults, 35 mm diameter, with press-stud connector, to be attached with adhesive rings 217 123 01
303 442 96	Adapter for electrode with press-stud connector to patient cable with 4-mm connector
504 648 56	Limb-lead electrode for adults (stainless-steel plate electrode), 31 x 40 mm, with 4-mm socket

301 340 00	Button-shaped electrode for adults, 30 mm diameter, with 4-mm socket
923 096 47	Rubber strap for attachment of electrodes 504 648 56 and 301 340 00
217 194 01	Chest electrode for chest belt, 30 mm diameter, with 4-mm socket
217 196 01	Chest strap for electrodes 217 194 01 and 301 340 00
217 144 01	Chest suction electrode, 22 mm diameter, small suction ball, with 4-mm socket
217 144 02	Chest suction electrode, 22 mm diameter, large suction ball, with 4-mm socket
919 202 32	Clamp electrode for limbs, pkg. of 4 electrodes (red, yellow, green, black)
9033-015	Suction electrode, small, German silver
9623-003P	Tab electrode SILVER MACTRODE plus, 1000 electrodes
9490-210	Clip adapter for SILVER MACTRODE, 10 adapters

NEHB Accessories

223 403 03	Patient trunk cable, 12-lead, NEHB, IEC
384 017 65	Set of 10 leadwires, IEC, with 4-mm connector
384 017 66	Set of 2 leadwires, NEHB, IEC, with 4-mm connector (in addition to 384 017 65)

Exercise Test Accessories

223 418 01	Patient trunk cable, 10-lead, IEC Multi-Link, 2.2 m
223 418 02	Patient trunk cable, 10-lead, AHA Multi-Link, 2.2 m
223 418 06	Patient trunk cable, 10-lead, IEC Multi-Link, 4.5 m
223 418 07	Patient trunk cable, 10-lead, AHA Multi-Link, 4.5 m
384 018 08	Set of 10 leadwires, IEC, Multi-Link, for electrodes with press stud
384 018 09	Set of 10 leadwires, AHA, Multi-Link, for electrodes with press stud
923 096 72	Exercise test belt
303 441 61	Patient cable hanger for ergometer
919 200 31	Disposable electrodes for adults, 200 electrodes

ECG Accessories, Cava Catheter

223 408 04	Patient trunk cable, 5-lead, for cava catheter
384 017 78	Set of 5 leadwires, IEC, for electrodes with press stud

Consumables

217 123 01	Adhesive rings, pkg. of 500, for electrodes 217 110 .., 217 320 .. and 217 321 ..
927 224 00	Adhesive rings, pkg. of 500, for electrodes 217 178 ..

217 083 18	Electrode cream, 250-ml refill bottle
217 083 14	Electrode cream, 5-liter container
930 115 82	Dispenser, 30 ml
217 083 06	Electrode gel, pkg. of 10 tubes, 100 ml each
217 083 05	Electrode cream, 10 tubes, 100 ml each
217 307 01	Electrode contact spray, 200-ml bottle
217 307 05	Electrode contact spray, 2-l bottle
217 007 01	Electrode paper, 200 sheets, for electrode 504 648 56
217 148 01	Electrode paper, 200 sheets, for electrode 217 144 01/02
217 043 02	ECG Filing Cards (50 pcs.)

Electrode Application Systems

216 121 01	Electrode Application System KISS 10 (10-lead, without pump)
216 122 01	Electrode Application System KISS 12 (12-lead (NEHB), without pump)
303 443 77	Swivel arm for KISS
384 015 84	Table-top clamp with pole
384 013 30	Wall fixture for swivel arm
303 444 21	Clip adapter for adhesive electrodes

Spirometry

208 019 01	Respiration Flow Sensor LF 501
928 056 62	Support for Respiration Flow Sensor
303 440 83	Disposable respiration filters (100 pcs.)

Ambulatory Blood Pressure Measurement

701 217 36	Connection cable TONOPORT IV to PC (25 pin)
701 217 37	Connection cable TONOPORT IV to PC (9 pin)
710 217 31	TONOPORT IV recording unit
710 217 32	TONOPORT IVa recording unit

For your notes

1. Installing the Program On A Stand-Alone PC

Do not install CardioSoft on your PC if you are not familiar with the Windows NT operating system!

Prerequisite for operation in conjunction with MUSE:
Install the Internet Explorer 4.0 and the Acrobat Reader, if you want to view test data stored in the MUSE CV database.

* Switch on the PC and the monitor. Exit ALL applications.

* Insert the CardioSoft CD in the CR ROM drive.

* Select “Start” —> “Run”.

* At the command line, enter
  X:\setup
  (X = CD ROM drive letter)

* Click “OK”.

* Select “Next” to confirm the suggested directory (when reinstalling the program, be sure to select the same drive).

CardioSoft will now be installed on your computer.

* Restart Windows.

We recommend to disable the Windows Print Manager to speed up printouts.

* Select “Start” —> “Settings” —> “Control Panel”.

* Double-click “Printer”.

* Select the printer you will use.

* Select “File” —> “Properties” —> “Scheduling”.

* Select “Print directly to the printer” and confirm with “OK”.

We recommend a resolution of 800 x 600 (15" monitor) or 1024 x 768 (17" monitor). For resolutions of 1024 x 768 or better we recommend to select “large font” in Windows – Setup – Display.

☞ ***The file V24.DLL is protected under the provisions of the copyright law. Copyright © 1992-1996 Langner GmbH. All rights reserved. Permission is granted to use the file V24.DLL only in combination with the CardioSoft program, and not in combination with any other program. Copying and making the file V24.DLL available to third parties is prohibited.***

Be sure to properly terminate the program before switching off the PC.

2. Operating the Program in Conjunction with a Medical Reimbursement Program / Clinical Information System (CIS)

CardioSys/Soft is supplied with a special BDT interface which allows it to be operated in conjunction with a medical reimbursement program or clinical information system. Please contact the supplier of these programs to find out about the conditions for full compatibility.

When running the program in conjunction with a medical reimbursement program, the patient data file is handled by the reimbursement program, whereas the procedure data files are handled by the Marquette Hellige program (CardioSys/CardioSoft). In this case patients are selected via the reimbursement program. The patient's height and weight should be entered in the reimbursement program, but they can also be added in CardioSys/CardioSoft.

Having selected the patient, you choose the procedure to be performed. This takes you automatically to the Marquette Hellige program, which is handled as described in this manual.

You can call up previous examinations of the selected patient and compare them or conduct new procedures, but you cannot select another patient. To do this, you have to quit the examination program first. Then you can choose a new patient in the reimbursement program.

After the procedure and quitting the examination program the most important procedure results (not the signal traces!) are transferred to the reimbursement program. Some of the reimbursement programs automatically suggest a bill.

Communication between reimbursement program and examination program:

– start of the reimbursement program

– selection of a patient

– display of file card

– selection of a procedure (start of the examination program)

– new procedures (ECG, spirogram, etc.)

– termination of examination program

– data transfer to reimbursement program.

When the Marquette Hellige program runs in conjunction with a reimbursement program, the following functions are disabled:

– selecting another patient, admitting a new patient

The following patient data are adopted by the reimbursement program: last name, first name, patient ID, date of birth, height, weight.

CIS Order List

Contact the supplier of the clinical information system to find out whether the program fulfills the requirements of the special Marquette Hellige data interface (BDT interface) and whether the program is capable of generating the so-called task list. Also, please contact Marquette Hellige to see whether the compatibility of the CIS has been determined by Marquette Hellige . If so, patients from the CIS database can be added to the task lists for the respective examination procedure types.

Upon activation of a procedure type, CardioSys/Soft will then allow you to select one of the patients from the corresponding task list (click on the “Order List” button).

At the end of the examination the clinical information system will adopt the data of the examination procedure, and the patient will be removed from the task list.

☞ ***Marquette Hellige is not in a position to guarantee full compatibility of all medical reimbursement programs/CIS with CardioSys/Soft.***

3. System Maintenance

The backup procedure described in the text below refers to the Marquette Hellige program only. The data of external programs, however, can be backed up in the same way.

3.1 Data Backup with Tape Streamer

We recommend making one backup of the operating system, and making daily backups of the CardioSys/Soft program and patient files.

Use the Windows backup application and refer to the online help for instructions.

* Insert the tape.
* On the Windows screen, select “Start” —> “Programs” —> “Administrative Tools (Common)” —> “Backup”.
* Select drive C or drive D.
* Click the Backup button.
* Enter the tape name.
* Check the “Verify after backup” checkbox.
* Enter some kind of information, such as “Backup date ...”.
* Select the backup method (for backups of the operating system “normal“, for the first backup of CardioSys/Soft data “normal“, for subsequent backups “differential”. When making a “differential” backup, select “append“, for normal backups select “replace”.
* Click the OK button.

The backup session begins. After the session, the backup will be verified.

* Click the OK button to clear the window.

Restoring Data from a Tape Streamer

* Insert the tape.
* On the Windows screen, select “Start” —> “Programs” —> “Administrative Tools (Common)” —> “Backup”.
* Open the Tapes window (icon in the bottom left-hand corner of the screen).
* Select the appropriate tape.
* Click the Restore button.
* Select the target drive.
* When restoring the operating system, select “Restore registry” and “Restore file authorization”. When restoring CardioSys/Soft and patient files, select “Restore file authorization”.
* Click the OK button.
* After the restore, click the OK button to clear the window.

3.2 Formatting Optical Disks

Before saving data to an optical disk, the disk must be formatted.

* Insert the disk.
* On the Windows screen, select “Start” —> “Programs” —> “Administrative Tools (Common)” —> “Disk Administrator”.

The disk administrator displays symbols for the different drives:
drive 0 = hard drive
drive 1 = optical disk (with free storage capacity)

* Click the “Drive 1” box.
* In the “Partition” menu select “Create” and confirm the max. storage capacity shown with OK.

The field for drive 1 now says “unformatted xxx MB”.

* In the “Partition” menu, select “Make changes now” and click “OK”.

The field for drive 1 now shows the drive letter, e.g. E.

* Check that the correct drive is selected (drive E in our example), because the formatting process will clear all data on the disk.
* In the “Options” menu, select “Format”.

* At “File system“, select “NTFS”.

* Enter a name for the optical disk.

* Click “Start” to initiate the formatting process.

* Click “OK” to confirm the message “All data will be cleared”.

Formatting takes about 5 minutes. A progress bar illustrates the process.

* Click “Close” to end the session.

* Close the Disk Administrator window.

4. The ECG Measurement and Analysis Programs

Refer to the following publications:

– ECG Interpretation Program HEART

– Marquette 12 SL Physician’s Guide

5. Direct FAX Transmission of Printer Documents

The documents usually sent to the printer can be directly routed to another PC or to a fax machine. Required accessories are a modem (recommended model: ELSA Microlink 14.4TQ) and the WINFAX Pro 4.0 fax software.

When installing the fax software from the program disk, you can configure the fax port as the standard printer. With this setting, every print command is sent to the fax program. Enter frequently used fax numbers in the “telephone directory”.
Select the “high” printer resolution, the A4 format and the landscape orientation. If the same image is transferred between 2 PC’s more than twice, you must select the portrait orientation after the second transfer.

If the modem is reserved for communication with the fax, there is no need for any special programming.

However, if it is also used for transmission of data from the ECG recorder to the PC, the init string should be modified accordingly (menu, fax program setup, fax modem):

example for the ELSA modem

AT&FX3&C1&D0S0=3\Q3\X0\:D1\ for telephone systems with extensions

AT&F&C1&D0S0=3\Q3\X0\:D1\ for direct dialling

Explanations:	AT	command start
	&F	default setting
	X3	for telephone systems with extensions
	&C1	identify connection
	&DO	ignore DTR status change
	S=3	fax answers after 3rd ring
	\Q3	RTS-CTS handshake, bidirectional

Sending the FAX

* Display the image to be printed.
* Initiate the printout.

The program converts the ECG into an image file. Depending on the computer model, this procedure may take several minutes. The printer status box indicates the page currently being converted. The fax software is activated automatically after the conversion.

* Select the addressee (entries in telephone directory).
* Select “Send”. The status window and the audible signals from the modem inform you of the transfer procedure.

After the transmission, the program hangs up automatically.

Only modems complying with the requirements of IEC 60950 or UL1950 may be connected to the system. Furthermore, the regulations applicable in the respective countries must be observed. The modem must be set up inside the medically used area, but outside the patient environment.

6. Connecting Peripheral Devices

Connecting the SunTech 4240 Sphygmomanometer

The sphygmomanometer needs to be configured once.

* When the program screen is displayed, select “Change Test Parameters”.

You move the cursor with the LAST ◀ and NEXT ▶ keys. You confirm entries with YES ▲.

* Confirm your selection with YES ▲.

* Select “Set BP Reading Interval” and press YES ▲ to confirm the selection.

* Set PRE, TEST and POST to MAN (using the YES ▲ or NO ▼ key, 1 to 90 minutes, MAN).

* Display the program screen again (press OK ▶ twice) and select “Utilities”.

* Confirm your selection with YES ▲.

* Select “Select System Interface” and push YES ▲.

* Select SUNTECH (with YES ▲ or NO ▼).

* Display the program screen again (press OK ▶ twice).

The setup is now complete (make a backup copy of the setup disk). From now on the Marquette Hellige program will start the sphygmomanometer.

Connecting the ERGOLINE 900/900L Ergometer

Adjust the following settings at the ergometer:

– EKG model P10

– baud rate 4800

The ergometer software must be version V436 or higher, or version V236 (call in an ERGOLINE specialist to install the latest version).

The round plug of the connecting cable is inserted in the “J10/RS232” connector at the ergometer. The other connector is plugged into CardioSys or the PC.

7. Application Tips

7.1 Artifact Due to Poor Electrode Application

This program is equipped with state-of-the-art electronic utilities to insure artifact-free recording. Among these are the automatic baseline adjustment and the cubic spline algorithm.

At the beginning of the recording the automatic baseline adjustment verifies the incoming signal and adjusts the baseline position accordingly.

During recording the cubic spline algorithm continuously checks the baseline position and returns the baseline to its normal level if it wanders.

When electrodes are not properly applied these measures may not fully compensate for artifact. High polarization voltages induced by electrodes applied without conductive gel may cause the amplifier to overrange, so that a straight line will be recorded instead of the ECG. Cubic spline will return this line to its normal position, and a baseline ensues for approx. 1 second (message Excess DC Offset).

Remedy

* Apply the electrodes according to instructions.
* Do not apply the electrodes on top of clothing.
* Use a contact agent (electrode cream, spray, etc.).
* Wait approx. 10 s before initiating a recording. After the 10-s period the automatic functions are enabled and the polarization voltages have stabilized, provided that all electrodes are properly applied.
* If it becomes necessary to verify the unprocessed “raw” ECG signal, switch off the Cubic Spline algorithm and all filters (40 Hz, AC filter) (refer to “Setup” in section 4.1.7).

7.2 ECGs of Pacemaker Patients

It is not possible to display pacing pulses directly. At a sweep or paper speed of 50 mm/s and a pulse duration of just 0.5 ms, the width of the recorded pacing pulse would be a mere 0.025 mm. For this reason the device reduces the pulse amplitude and expands the pulse width, so that the pacing pulse is easier to identify. The pulse is displayed with the correct polarity and a width of 5 ms (depending on the polarity of the pacing pulse in leads I and II, the pacing pulse in lead III may be suppressed). Figure 7-1 shows an ECG recording with pacing pulses.

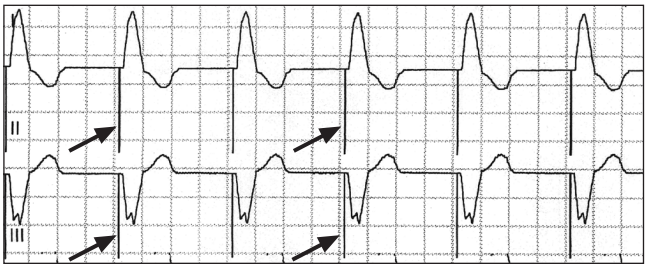


Figure 7-1. Display of pacing pulses

☞ ***If several adverse conditions exist at once, the possibility of pacing pulses being interpreted as QRS complexes should be considered. At the same time, however, QRS complexes might be suppressed in certain situations. For safety, always watch pacemaker patients closely.***

7.3 ECG Recording During Defibrillation

The patient signal input is defibrillation-proof. Therefore it is not necessary to remove the ECG electrodes during defibrillation.

When using stainless steel or silver electrodes, however, the defibrillator discharge current may cause complete polarization at the electrode/skin interface. This will block acquisition of the ECG signal for several minutes. This can be avoided by using silver/silver-chloride electrodes.

If electrodes made of other materials are used, we recommend disconnecting the patient cable from the recorder while the shock is applied.

Disable the Cubic Spline algorithm that would cause a signal delay of 4 seconds, if defibrillation will be carried out during ECG recording (section 4.2.7 “Exercise-Test Setup”).

☞ ***Use only silver/silver-chloride electrodes for ECG acquisition to ensure optimal performance during defibrillation.***

7.4 ST/HR Slope Value

The ST/HR slope was originally developed by Dr. R.J. Linden at the University of Leeds, United Kingdom in the late 1970s. It is reported to yield more accurate electrocardiographic determination of the presence and severity of coronary heart disease. While originally applied only to bicycle ergometry testing, it has recently been adapted for treadmill exercise by Dr. Paul Kligfield and colleagues at Cornell University.

The criteria are based on the near parallel increase of myocardial oxygen demand and heart rate with increasing effort. Essentially, the exercise electrocardiogram is evaluated by linear regression analysis of the rate-related change in ST depression as measured at 60 ms post J point. Originally, the 12 classical leads and bipolar lead CM5 were evaluated. Changes in leads aVR, aVL, and V1 have been found to be poorly specific and are currently ignored. The addition of lead CM5 improves sensitivity appreciably.

A plot of ST segment depression versus heart rate is drawn for all measured leads. Linear regression analysis is used to best fit a line beginning at peak exercise and extending backward through at least three points until significance is obtained ($p < 0.05$). The points are taken from the ST level and heart rate at the end of each 2-minute exercise stage. The slope of this line is then determined and presented in units of µV/BPM. The steepest slope of all the leads is reported and graphed.

The large increments in heart rate between stages of the Bruce protocol were found to yield an inadequate number of points for proper slope evaluation. A modification of the Bruce protocol (half work loads in 2-minute exercise stages) more closely approximate the roughly 10 beats per minute increments found in ergometry testing. This protocol, developed at Cornell University by Okin, et al, is reproduced here and is strongly recommended for the highest predictive accuracy.

Exercise Stage (min)	Speed (mph)	Grade (%)
2	1.7	0
2	1.7	5
2	1.7	10
2	2.1	11
2	2.5	12
2	3.0	13
2	3.4	14
2	3.8	15
2	4.2	16
2	4.6	17
2	5.0	18
2	5.5	19

Table 1. Cornell Treadmill Protocol for ST/HR Slope

7.5 External Sphygmomanometers

CardioSys supports blood-pressure measurement with the following sphygmomanometers:

– SunTech 4240 (BP Meter 1), specially suitable for treadmill applications

– bosotron 2 (BP Meter 2), specially suitable for bicycle applications

The sphygmomanometer is connected to a serial interface. Select the appropriate port on page 2 of the defaults menu (section 4.2.7 “Exercise-Test Setup”).

The sphygmomanometer must be ready for use before the exercise test is activated. If this is not done, the system will not recognize the BP meter and prompt you to take a manual blood-pressure measurement.

If the system takes longer than 60 seconds to complete a measurement, the readings may appear at the next stage or phase. You can avoid this problem by waiting at least 40 seconds after display of the BP readings before starting the exercise test.

☞ ***If the systolic pressure is expected to exceed 200 mmHg, increase the deflation rate at the sphygmomanometer to reduce the measuring time. The bosotron 2 device aborts measurements after 90 s.***

If an external sphygmomanometer is not connected, select the blood-pressure meter integrated in or connected to the ergometer from the defaults menu.

marquette
HELLIGE
MEDICAL SYSTEMS

EC Declaration of Conformity

Document No. 7-97

Marquette Hellige GmbH, Munzinger Strasse 3, D-79111 Freiburg, Germany

We herewith declare that the product

ECG analysis system, cardiograph CardioSys, product status **Version 3.0**

fulfills the requirements of the following directives, standards and normative documents:

1. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

2. EN 60601-1:1990 / DIN VDE 0750 Teil 1/12.91 / IEC 601-1 2. Ausgabe 1988
   EN 60601-1-1:1993 / DIN VDE 0750 Teil 1-1/09.94 / IEC 601-1-1:1992
   E DIN IEC 62(Sec)73:1995-02 / IEC 62(Secretariat)73:1994
   IEC 601-2-25:1993 / E DIN IEC 601-2-25 (Klassifikation VDE 0750 Teil 2-25):1994-11

3. EN 60601-1-2:1993 / DIN EN 60601-1-2:1994-09 / IEC 601-1-2:1993
   EN 55011:1991 / DIN VDE 0875 Teil 11:1992-07 / CISPR 11:1990 modified,
   device group 1, **class B**

Compliance of a representative sample of the designated product with the "essential requirements" of Annex I of the Directive 93/42/EEC has been certified by the Notified Body

VDE Testing and Certification Institute, Merianstr. 28, D-63069 Offenbach, Germany
EC Type Examination Certificate No. 1009 of 4 April 1995.

The medical device has been assigned to class **IIb** as specified in Annex IX of the Directive 93/42/EEC. It bears the mark

CE-0366

The designated product has been designed, manufactured and tested under a quality management system according to DIN EN ISO 9001, EN 46001 and Annex II Section 3.2 of Directive 93/42/EEC concerning medical devices. The conformity of the quality management system has been certified by:

VDE Testing and Certification Institute

Freiburg, 27 June 1997
Marquette Hellige GmbH

Dr. Matthias Weber, Director
Marketing & Engineering

The technical documentation
is filed in the RA/QA Dept.
(...\csy_30_e.doc)

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